

REC'D 18 OCT 2004
WIPO PCT

Patent Office Canberra

I, JULIE BILLINGSLEY, TEAM LEADER EXAMINATION SUPPORT AND SALES hereby certify that annexed is a true copy of the Provisional specification in connection with Application No. 2004901625 for a patent by DAVID PETER WHARTON as filed on 26 March 2004.



WITNESS my hand this Eighth day of October 2004

JULIE BILLINGSLEY

TEAM LEADER EXAMINATION

SUPPORT AND SALES

PRIORITY DOCUMENT

SUBMITTED OR TRANSMITTED IN COMPLIANCE WITH RULE 17.1(a) OR (b)

BEST AVAILABLE COPY

P/00/009 Regulation 3.2 Revised 12/98

# AUSTRALIA Patents Act 1990

## PROVISIONAL SPECIFICATION

for the invention entitled:

"Medication holder"

The invention is described in the following statement:

#### TITLE

#### "MEDICATION HOLDER"

### FIELD OF THE INVENTION

THIS INVENTION relates to a device for securely storing a container holding medication for use by a person. In particular, the invention relates to a device for holding medication provided for inhalation or ingestion. The device is particularly suitable for use by a person when mobile and may be well suited for use during sporting activities, but is not so limited. Operation of the device facilitates access to the medication for administration.

## 10 BACKGROUND OF THE INVENTION

15

20

The evolution of devices for self-medication has been of great advantage to sufferers of various diseases and pathologies.

One prime example is that of asthma. In earlier times, sufferers of asthma were typically sentenced to a lifetime of disability, often based on arranging their life around low levels of physical activity or restricted ranges of travel, so that they could be close to support mechanisms provided in their own environment. Severe bouts of asthma often required the attention of professionals, such as doctors, and the use of drugs administered by those professionals. These drugs, which included aminophylline and adrenaline, had reasonable levels of efficiency but also brought with them some significant risks of use. Further, the use of these drugs was a late stage step in the process and did not provide any ongoing advantage to a patient in the way of control and stabilisation of the disease condition.

The development of corticosteriods was of great assistance in some diseases and, in particular, asthma. However, the side effects of prolonged oral or parenteral administration of corticosteroids in people are notorious and necessitates restrictions on the adoption of this approach in other than the most severe cases.

5

15

20

A dramatic improvement in the quality of life of sufferers of asthma arose with the development of pressurised medicated containers designed for the self-administration of salbutamol, a bronchodilator, which is very effective in counteracting the bronchospasm of an asthma attack. Salbutamol is usually provided in a pressurised container with a depression-activated valve at its top. The valve is configured to nest in a seat provided on an outer plastic collar, cap or mouthpiece. This collar allows the depression of the canister relative to a valve stem, thereby releasing a controlled dose of therapeutic agent into a discharge throat of the collar. A patient uses the device by exhaling to a greater or lesser extent and then inhaling while depressing the canister to discharge a dose of the agent.

As well as providing the ability to treat an attack of respiratory embarrassment, the salbutamol inhalers have provided the ability to self-administer a regime of treatment to thereby minimise clinical signs and allay or prevent further development of the respiratory attack.

Salbutamol is an excellent example of a suitable therapeutic agent for selfdelivery but is by no means alone. Many other forms of therapy have been provided for asthma (for example, Becotide, Flexitide, Asmol). Additionally, many other diseases lend themselves to self-medication through the provision of a metered dose, either into the respiratory tract or for ingestion through the gastrointestinal tract or absorption through the mucous membranes of the oropharynx or the nose.

Provision of the medication may be in a form as described, being a compressed pressurised aerosol formulation. Alternatively, powder or other solid formulations or even liquids or gases may be provided and dispensed at a set dose. Separate individual doses of medication may be provided in a capsule or similar form and adapted for release in devices often referred to as medihalers. These devices may have a rotatable vane which is activated by a patient breathing in, thereby distributing the medication into the airstream. In some arrangements a fine powder may be simply breathed into the lungs.

10

15

20

While these developments have been of tremendous utility to sufferers of diseases that lend themselves to effective self-medication, there has been an ongoing problem of patients either forgetting their medication canisters or mistakenly believing they are stored somewhere, such as a handbag or sports bag, only to find the medication is not available for use when required. This can, of course, have serious consequences in the event of a sudden severe onset of disease signs and symptoms. The problem of effectively and safely storing medication canisters is exaggerated in sporting activities where clothes are often designed for the specific requirements of the sport being undertaken, but with no provision of secure pockets or pouches. Even when pockets are provided, the presence of a hard object carried in such a pocket may be uncomfortable, irritating or even performance-restricting in a competitor. The problems may be pronounced in activities, such as snorkelling, scuba diving, orienteering and mountaineering where a sufferer of a

condition may find themselves a considerable distance from a support based with little else other than gear required for the activity.

Reference to any prior art in this specification is not, and should not be taken as, an acknowledgment or any form of suggestion that this prior art forms part of the common general knowledge in any country.

## SUMMARY OF THE INVENTION

In one form, although it need not be the only or indeed the broadest form, the invention resides in a housing for a medication canister or arrangement, the housing comprising:

a first wall defining a cavity dimensioned to receive and enclose, at least in part, the medication canister or arrangement;

a second wall abutting the first wall and moveable relative thereto; wherein:

the second wall may be positioned in a first closed position or, alternatively,
in a second open position, the second open position providing or facilitating access to a
medication discharge outlet of the medication canister or arrangement.

The first wall may be an inner wall. The second wall may be an outer wall in a sleeved relationship to the inner wall. "Enclose, at least in part, the medication canister or arrangement" may comprise sealingly enclosing the canister or arrangement through an encircling wall or a wall that elastically abuts against a wall of the canister or arrangement to resist ingress of moisture or other contaminant.

20

The housing may be formed from any suitable material, but is preferably formed from a durable polymer such as PVC, PEEK or PET or an alloy such as aluminium.

The housing is preferably formed of components that may be moulded or extruded.

The medication canister or arrangement may comprise a pressurised canister. The canister or arrangement may be adapted to release a controlled dose of therapeutic agent. The canister may preferably contain multiple doses of the therapeutic agent. The medication canister or arrangement may be understood to extend to a mechanism that is pressurised or activated by the through flow of air inhaled by a user. This may include a rotatable impeller. The medication canister or arrangement may comprise a frangible container that is able to be ruptured to release the therapeutic agent. The canister or arrangement may be one or more ampoules which may be conveniently formed from glass or plastic.

10

15

20

The first inner wall may define an enclosed bore dimensioned to receive the medication canister or arrangement. The first inner wall may be a continuous wall. The bore may be open at one or both ends. A first end region of the first inner wall adjacent a first opening may be adapted to engage a flexible membrane. The flexible membrane may be formed as a concertina-type membrane. The flexible membrane may be engageable with the first end region in a watertight or water-resistant manner. The flexible membrane may be adapted for transferring a depressing force from a user's hand to the medication canister to activate it when aligned for use. The flexible membrane may be formed as a thumb pad.

Alternatively, the first end region may be formed as a closure of the bore, the closure operable to provide an air flow pathway through the bore. The closure may be twist operated and may be also adapted to advance a medication dose into position for inhaling.

5

10

20

The medication arrangement may comprise a depot of medication and dispersal means for distributing the medication for ingestion or inhalation. The dispersal means may be a rotatable vane or impeller. The depot may comprise one or more capsules, each storing a dose of medication and arranged to rupture when in position for dispersal. The medication arrangement may comprise an evaporation surface to facilitate evaporation of a volatile material. The evaporation surface may be formed by an absorbent material which is preferably arranged in one or more folds to increase the evaporation area. The evaporation area may be formed by one or more panels forming a surface over which inhaled air flows.

A second end region of the inner wall may abut a second end aperture of the bore. The second end aperture may be formed as a lateral aperture.

Preferably, the bore contains a mouthpiece which may be adapted to receive a valve end of the canister. The mouthpiece may comprise a seat for receiving the canister and a medication channel adapted to direct a dose of medication in a desired direction. Alternatively, the mouthpiece may comprise the medication channel.

Preferably, the mouthpiece is pivotally mounted and rotatable between a first stowed position and a second deployed position, wherein the medication channel is positioned to deliver medication to a user. The mouthpiece may be pivoted between the stowed and deployed positions manually. Preferably, the mouthpiece is biased towards the

deployed position. The mouthpiece may be urged to a stowed or deployed position by movement of the second wall in a first or second opposite direction, respectively. The mouthpiece may be biased towards the deployed position by spring means. The mouthpiece may include an air intake vent. Alternatively or additionally, the first and/or second side walls may include an air intake vent which is preferably sealed when not in use.

The inner wall may define an end region of the housing.

10

The inner wall preferably is dimensioned to provide a recess or recesses to hold one or more additional medication canisters. The one or more additional medication canisters may be stored substantially parallel to the medication canister.

The outer wall is preferably movable relative to the inner wall by sliding. The outer wall may be formed as a sleeve member for partially or completely encircling the middle wall for at least a portion of the inner wall's length. Preferably, the outer wall is slidable into a closed position abutting an end planar region of the housing and an open position in a direction away from the end planar region. The second wall may be removed during operation. Preferably, the outer wall remains attached to the inner wall during use. Most preferably, the outer wall remains in a sleeved, abutting position with the first wall during use.

The housing may include sealing means for providing a water-resistant seal between the outer and inner walls, particularly when the outer wall is in a closed position. The sealing means may comprise one or more seals, preferably O rings, positioned in either the outer wall or the inner wall, especially in the outer wall.

The housing preferably further comprises attachment means for attaching the holder to an item such as a sports bag or, preferably, to a user. The attachment means may be an eye and strap arrangement for positioning the device around the neck of a user or around a portion of a sports bag or similar.

Preferably, the attachment means is a band adapted for positioning around the limb of a user or around a strap of a bag or similar. The band is preferably a wristband. The housing may be attached to the wristband in any suitable fashion. In its most basic form, the band may be required to be removed for use of the medication canister.

5

10

15

20

Preferably, however, the housing is fixed to the band by a pivot fitting which permits the housing to be rotated between a first position, wherein it is substantially aligned with the longitudinal axis of a user's arm and a second position where it is substantially transverse to the longitudinal axis and thereby accessible for easy use.

The band may be fixed by any standard means, such as a buckle or Velcro strap. The band may be elasticised. The band may further incorporate other items such as a diving watch, stopwatch, alarm or other items sometimes required during outdoor and sporting activities.

Alternatively, the housing may be fixed to a clip in a demountable manner, the clip adapted to engage a support item. The support item may be a belt, band, strap, waistband, pocket or similar. The housing may engage the clip through a snapfit connector.

In another aspect, the invention resides in a housing for a medication canister or other arrangement, the housing comprising:

a first wall defining a cavity dimensioned to receive and enclose, at least in part, the medication canister or arrangement; and

a second wall engaging or abutting the first wall and moveable relative thereto;

wherein the second wall may be connected to the first wall and adapted to move between a first closed position and a second open position providing access to a medication discharge outlet of the medication canister or arrangement.

5

15

20

The medication canister or arrangement may include a frangible ampoule or vial and may further include an evaporation surface. The evaporation surface may be formed by a material wick or element.

The second wall may be connected to the first wall by a tether arrangement.

Preferably, the second wall is connected to the first wall by a pivot arrangement.

In a further aspect, the housing may include a support engageable with a strap, belt, item of clothing or similar. The support may be demountable from the other housing components.

#### BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 is a front view of a preferred embodiment of a housing of the present invention incorporating a spare medication canister;

FIG. 2 is a sectional arrangement of FIG. 1;

FIG. 3 is a front view of the arrangement of FIG. 1 when deployed for use;

FIG. 4 is a perspective view of the arrangement of FIG. 3;

FIG. 5 is a front view of a second embodiment of a housing for a single medication canister;

FIG. 6 is a sectional view of the arrangement of FIG. 5 when inverted for use;

FIG. 7 is a sectional view of the arrangement of FIG. 6 when deployed for

FIG. 8 is a side sectional view of a further embodiment of a housing of the present invention;

FIG. 9 is a side view of the housing of FIG. 8;

use;

FIG. 10 is a side section view of the arrangement of FIG. 8 when configured for use;

FIG. 11 is a perspective view of the configuration of FIG. 10;

FIG. 12 is a sectional view of yet another embodiment of a housing;

FIG. 13 is a front view of the housing of FIG. 12;

FIG. 14 is a side view of the housing of FIG. 13;

FIG. 15 shows the housing of FIG. 13 when ready for use;

FIG. 16 is a preferred embodiment of the arrangement of FIG. 2 when mounted to a wristband;

FIG. 17 is an exploded view of the arrangement of FIG. 16.

FIG. 18 is a perspective view of a further embodiment of a housing for a medical canister;

FIG. 19 is an exploded view of the canister of FIG. 18 in use;

FIGS. 20 and 21 show the operation of the arrangement of FIG. 18;

FIG. 22 is a perspective view of a further embodiment of a medical housing;

FIG. 23 is a view of the medical housing of FIG. 22 in position on a user's arm;

FIG. 24 is a schematic view of possible positions for the medical canister on the body of a user;

5

20

FIG. 25 is front view of an arrangement for holding two medical canisters;

FIG. 26 is a series of views of still another embodiment of a medical housing;

FIG. 27 is a series of views of the medical housing of FIG. 26 in operation;

FIG. 28 is a series of views of another embodiment of a medical housing of

10 the present invention;

FIG. 29 is a perspective view of a further embodiment of a medical housing of the present invention;

FIG. 30 is a sectional side view of the medical housing of FIG. 29;

FIG. 31 is a perspective view of a further embodiment of the medical housing of the present invention;

FIG. 32 is a perspective view of the housing of FIG. 31 when arranged for storage;

FIG. 33 is a series of views of still another medical housing of the present invention;

FIG. 34 is a series of views of the embodiment of FIG. 33;

FIG. 35 shows two perspective views of a counting or indicating arrangement in a medical housing of the present invention;

FIG. 36 is a side view of the arrangement of FIG. 35;

FIG. 37 is a perspective sectional view of the arrangement of FIG. 36 in position;

FIG 38 shows views of an arrangement similar to that of FIG 34 including an absorber.

#### DETAILED DESCRIPTION OF THE DRAWINGS

5

10

20

Referring to FIG. 1, there is seen a housing which in this case is exemplified by a medication holder 10 comprising an inner wall 11 and outer wall 12.

The inner wall 11 is formed as a continuous wall and is substantially in the shape of a figure 8 arrangement in cross-section. An intermediate recess 13 defines the border between a first active bore 15 and second storage bore 16.

A first end region 17 of the active bore 15 is capped with the flexible membrane 18, which may also extend across the end of the storage bore 16 to thereby seal both bores. The storage bore 16 may be capped by a separate cap 19 to provide independent operation of the two capping mechanisms. However, in general, it is envisaged that the end capping arrangement would be continuous to allow easy removal and subsequent positioning of a fresh canister in the active bore 15 with subsequent recapping for use. It should be noted, however, that the device may be able to be used without the end cap at all. The wall of the first bore 15 may be attached to a flexible skirt-like structure (not shown) with an aperture for receiving and snugly adjoining the wall of the medical canister. A resilient diaphragm may be positioned in the bore to sealingly engage the wall of a canister to thereby isolate the mouthpiece and render it waterproof.

In some embodiments, the canister may comprise an arrangement for delivering a solid therapeutic agent, such as in powdered form, or indeed a liquid therapeutic agent. In this case, it may be desired to have a through bore which is patent and allows the inspiration of air flowing through the bore and canister arrangement to activate a spinhaler or similar and disperse a therapeutic agent. The through bore may also be provided for use with a pressurised canister. The spinhaler may be provided with powder carried in a separate capsule or similar arrangement. The capsule may be mounted in a seat in the bore and pierced to release powder for subsequent inhalation. In this case, the storage bore may in fact be adapted to store solid medication, preferably in the form of powder. The powder may be in individual doses formed in gelatin capsules or similar. Alternatively, the powder may be provided as a bulk quantity with a measuring spoon for loading into the active bore. The term "medical arrangement" therefore can be viewed as extending to these arrangements which provide a means of medicating an airstream delivered to the mouth or nose. The through bore may be usually closed and only opened during operation of the device.

10

15

20

In this embodiment, a neck strap 20 is shown mounted to a receiving eye 21. The neck strap allows the positioning of the housing 10 around the neck of a user. In the subsequent discussion, it will be seen that a user may simply slide the outer wall 12 into an open position with the holder inverted for immediate and easy use.

The internal arrangement of the device of FIG. 1 can be seen in FIG. 2. A first pressurised metered dose inhaler 22 is positioned in the active bore 15.

The flexible membrane in the form of a cover cap 18 is seen to be an integral unit which sits above an activation button 23. The canister 22 has a valve stem 24 positioned in a seat 25 in a cap or mouthpiece 26. The valve stem has a discharge channel 27 leading to a discharge aperture 28 in the mouthpiece or top cap 26. The mouthpiece 26

is pivotally mounted on stud 29 and tensioned by a spring 30. The spring 30 biases the mouthpiece into a deployed position. O ring seals 31 are provided to resist the ingress of moisture and water during use. The presence of the seals is preferred as it lends great utility and robustness to the holder, thereby making it suitable for use in wet environments, in forest and bush settings, in mud and around dust and other potentially dangerous environmental features. The seals are located between the two walls and may be formed of any suitable polymer such as rubber or silicon-based material. Preferably, the seals provide a limited resistance to the sliding of the outer wall 12 over the inner wall 11.

A spare canister 32 is seen in position. The canister may contain the same agent as the pressurised dose canister 22. Alternatively, the canister may contain a different therapeutic agent, thus allowing the holder to provide alternative forms of medication. It is also clear that the holder may be designed to carry two or more spare canisters, each being a duplicate or a source of an alternative therapeutic agent.

FIG. 3 shows a front view of the arrangement of FIG. 1 with the outer wall

12 slid into its open position, thereby clearing the bore containing the canister. The bore also provides space 33 for location of the mouthpiece 26 when in rotated stored position.

The mouthpiece 26 is directed outwardly of the medication holder and positioned for easy access by a user. The mouthpiece may include an air intake vent or vents (not shown) to provide inhalation air when a user places his or her lips on the mouthpiece. The mouthpiece may comprise the seat 25 and medication channel formed as the discharge chute.

20

FIG. 4 provides a further perspective view of this arrangement.

FIG. 5 shows an embodiment in which a single canister is installed in the medication holder 40. An inner wall 41 is surrounded by an outer wall sleeve 42 for a portion of its longitudinal length. This embodiment again has a neck strap 43. It also has a concertina-like flexible membrane cap 44 on a first end of the inner wall 41.

While it is generally preferred that the inner and outer walls are formed from the same material, it is possible to use different materials for each of the components. The walls may be formed from lightweight durable polymers but could also be formed of metal. The outer wall 42 is shown with grip-enhancing pads 45 to facilitate use.

· 5

.10

While emphasis has been placed on the use of therapeutic agents, it is also clear that the medication holder may store non-medical agents such as vitamin supplements, energy-boosting substances, electrolyte replacements and similar. One example of such a material may be glucose for diabetes sufferers for use in the event of a hypoglycaemic episode arising. Simple application of glucose may be sufficient to raise the blood glucose levels and prevent the risk of hypoglycaemic signs including the life-threatening possibility of a hypoglycaemic coma. While such a person would clearly be suffering from a disease condition, the use of glucose in endurance athletes or for athletes in extreme conditions may be of considerable advantage in maintaining their homeostasis and circulatory equilibrium in an otherwise fit and pathology-free person. The medication may be directed to gastrointestinal absorption as opposed to respiratory tract targeting.

FIG. 6 shows the arrangement of FIG. 5 inverted and in a stowed position.

The canister 46 is apparent, as is the mouthpiece 47 and O ring seals 48.

In FIG. 7, the outer wall 42 has been slid in the upward direction of arrow 49, cleared the bore 50 and allowed the mouthpiece 51 to pivot in the direction of

arrow 52. This time, pivoting is in a front-to-back direction around pivot pin 53 and under the effect of spring 54. The holder 40 therefore does not require lateral storage space in the bore and allows storage of the mouthpiece in an up and down bore under the end or top region 55.

5

10

20

An alternative embodiment is shown in FIG. 8 in which the housing is exemplified by a medication holder 65 having an outer wall 66 and inner wall 67, the latter inner wall 67 forming a bore 68. A wad of moisture absorbing material 69 is placed in the bore next to an end twist base 70. A dry powder reservoir 71 is provided which is formed by a concentration of medication material. A secondary reservoir 72 contains a single dose of the powder and is refilled from the reservoir 71. A mouthpiece 73 is stowed by rotation around pivot point 74 with the outer wall 66 positioned to retain it in a retracted location as shown. O ring seals 75 provide a barrier to ingress of unwanted materials. A flow path 76 is formed to lead away from an inhalation area 77.

FIG. 9 shows a view of the device 65 with an arrow 78 indicating the direction in which the outer wall 66 will slide relative to the inner wall in operation. It is within the concept of the invention to reverse the inner and outer walls and have the inner wall slide inside the outer wall to release the mouthpiece.

FIG. 10 shows the mouthpiece 73 rotated around the pivot point 74 and in working position relative to the flow path 76. The end twist base 70 may be rotated to move the dose in the secondary reservoir 72 into the inhalation area 77. Rotation of the twist base 70 opens and creates a patent air pathway from the twist base 70 through to the mouthpiece 73. A user may then inhale through the mouthpiece 73 pulling air through the device and entraining the powdered medication for subsequent inhalation. Further doses of

the compound may be provided by additional twisting of the twist base, preferably in a reciprocating action.

FIG. 11 shows the components as seen in a perspective. In this case, the twist base forms a closure but when activated provides a patent air path through the device. An end section 78A acts as a top cap for the medication holder.

5

A cross section of yet a further embodiment of a housing is shown in FIG. 12 in which a medication holder 80 is seen in side sectional view. The medication holder 80 has a mouthpiece 81 and drug delivery point 82.

A geared arrangement shown generally as 83 is configured to operate a blister pack roll 84 formed of a flexible backing material with blister packs containing predetermined doses of medication. Operation of the geared arrangement 83 may be through the action of sliding outer wall 85 over the inner wall 86 thereby causing rotation of the gears, advancement of the blister pack roll 84 and rupture of one blister pack at the drug delivery point 82 to present the medication for inhalation. The device may be provided with a neck strap attachment 87.

FIG. 13 shows the device in side view with finger grips 88 apparent.

FIG. 14 shows the slim line nature of the device which allows it to be formed as an easily carried and unobtrusive but fully closed package.

FIG. 15 shows the medical hold 80 with outer side wall 85 slid out of alignment with an O-ring seal 89 thereby exposing the mouthpiece 81 allowing a user to access it and inhale the medication provided from the ruptured blister pack. Movement of the wall 85 both advances the blister pack roll as well as clearing an aperture to permit through flow of air once a user inhales while engaging the mouthpiece.

FIG. 16 shows a preferred embodiment in which a medication holder 60 is rotatably mounted to a wristband 61, in turn, mounted on the arm 62 of a user. The holder may be rotated in the direction of arrow 63 for deployment for use. When not in use, the longitudinal axis of the holder 60 is substantially parallel with that of the arm 62, thereby providing a neat and non-extruding profile when being carried by a user. When required, the holder 60 may be rotated through 90° and the outer wall 64 slid clear of the aperture leading to rotation and presentation of the mouthpiece (not shown). In this orientation, a user may simply bring his or her forearm up to alignment with the user's mouth or nose. In this case, the outer wall 64 may have a slotted underside to allow movement relative to the pivotal mounting. Once used, the outer wall 64 may be then slid back into a closed position and the holder rotated back through 90° for its carriage position. The method of attachment to the wristband may be any suitable arrangement such as friction plates or rotation plates with indentations for preferred positioning.

10

20

While a straightforward band 61 is shown in this view, it is clear that mounting arrangements may be fixed to other items commonly worn on the wrist such as watches, depth gauges, stopwatches, altimeters and heart rate monitors

The arrangement of FIG. 16 is shown in exploded view in FIG. 17 of the medication holder 60 coupled to a wrist mount attachment 90 which in turn fits into a seat 91 on a plate 92 which is continuous with wristband 61. Small lugs 93 act as stops to resist rotation. Use of appropriate rotational force will overcome this resistance and cause the medication holder to rise up and rotate through 90° to the next lug. Additional force may keep the device rotating but it is envisaged that a range of 90° will be adequate to discharge the function of the device.

The present invention provides a considerable number of advantages. A medication source may be easily and conveniently carried by a person in virtually any circumstance. A preferred circumstance is in the sporting or outdoor arena where the medication holder may be formed as a substantially waterproof item with robust and hardwearing characteristics that make it difficult to damage while providing easy and instant access to a hygienic and ready-to-use medication source. Many people with asthma have a degree of embarrassment about the use of inhalers and similar and in publicly displaying their canisters. The present invention provides an effective way of carrying the canister in a fashionable and stylish way which may address at least some of this inhibition. The housing may be provided in a coloured arrangement with or without advertising indicia and may be labelled with information on the drug housed within. They may be provided by sports promoters or pharmaceutical companies as well as made available for private purchase. The medication holder may be used in sports in a wide range of terrains and, in fact, in any terrain or environment that is accessible by a participant. Carrying or wearing the medication canister or even locating it in association with a carried item or object will lead to minimal or no interference with performance by an athlete.

10

15

20

While the emphasis is on sports use, it is also clear that any potential user of a medication carried in a canister may find a reason for and advantage in using the present housing.

Referring to FIG. 18, there is seen an embodiment of a housing 100 which incorporates a locking recess 101 in a housing support 102 which is formed in a roughly triangular fashion terminating in a top ridge 103. The top ridge 103 has a recess 104. The

recess 104 has a stud adapted to mount into a dimple 105 formed in a fin 106 on the top of the housing 100.

This arrangement allows rotation of the housing 100 relative to the support 102. The support in turn is mountable onto spigot 107 formed on base plate 108 mounted to the wrist 109 of a user by strap 110.

5

10

In FIG. 20, the medical housing 100 is aligned along a user's arm and fixed to the strap 110. It is therefore easily and safely carried with little opportunity to inhibit the user in his or her usual activities. When required for use, the housing 100 may be pivoted in the direction of arrow 111 to the position shown in FIG. 21. The outer wall 112 may then be slid in the direction of arrow 114 to expose the operative components including the mouthpiece. A medicated dosage inhaler may be depressed to eject a therapeutic substance into a user's mouth or nose while raising the wrist to place the chute in an effective position.

FIG. 22 shows a perspective view of a similar arrangement in which the medical housing may be rotated relative to the support 102 and may even simply be disconnected from the support for easier use. In this case, the support does not have a locking recess but rather has a slot 115 formed by a resilient flap 116 and dimensioned for easy location over a strap, belt, the edge of a pocket, top of a shirt or similar.

The operation of the embodiment of FIG. 22 is shown in FIG. 23 where the slot 115 is slipped onto the strap 117 and the medical housing 100 is held in position. In use, the housing 100 may simply be rotated away from the support 102 and disengaged. After use, it may then be snapped back into position.

A wide range of positions may be used as shown in FIG. 24. Representative positioning includes the shoulder, around the neck or chest, on an upper arm, on top of the wrist, under the wrist, on a belt or waistband, in a pocket or on clothing or around the ankle. Other positions may also be suitable.

FIG. 25 shows a frame 118 designed to receive two medical housings 119, 120 simultaneously. The housings may be connected to the frame through hooks 121, 122, respectively. The frame 118 may have a loop 123 formed to receive a belt or other carrying arrangement such as a strap.

5

10

FIG. 26 shows a series of views of a medical housing 200 with a slip on support 201 with resilient flap 203 defining slot 204. The housing has an internal canister 205 which discharges into mouthpiece 206.

The arrangement of FIG. 26 is shown in operation in FIG. 27 where side wall sleeve 207 has been slipped down to reveal the mouthpiece 206 which is positioned below the mount 201 allowing ready access for a user.

FIG. 28 shows a further medical housing 300 with a mouthpiece 301 that is moved in and out of deployment by pivot arm 302 positioned to co-operate with slot 303. In operation, the sleeve 304 is slid in the direction of arrow 305. The mouthpiece 301 is in a retracted stowed position until an internal lug on the sleeve 304 contacts an extension piece of the pivot arm 302 and causes the latter's rotation. As the pivot arm rotates, it leads to deployment of the mouthpiece 301A as it slides up the slot 303. When the sleeve 304 is slid in the reverse direction, it again encounters the extension piece and causes the pivot arm to rotate in the reverse direction, thereby urging the mouthpiece 301

back into its stowed position allowing the sleeve to sit over the top of it and seal it from the environment.

FIG. 29 shows a further embodiment of a medical housing 400 in which the external wall 401 is formed substantially as a cap to sit over an open bore conduit 402 which receives a medical canister 403. The device is seen in sectional view in FIG. 30, where the open bore of the conduit 402 is closed by the canister 403 and a sealing member 404 in the form of an O ring. An internal ridge 405 may also be provided to assist in retaining the canister 403 in position. The cap 401 is hingedly mounted to the conduit by a strap 407 and hinge point 408. The strap 407 has a button 409 designed to locate and occlude aperture 410 in the conduit 402.

5

10

15

20

In operation, the cap 401 is rotated around by grasping the tab 411. The cap is removed by pulling the button 409 from the aperture 410 creating an air pathway when used. This overcomes a problem created by the presence of O ring seal 404 which would otherwise prevent passage of air and mixing with an ejected plume of therapeutic agent.

FIGS. 31 and 32 show a further arrangement of a medical housing 500 in which a discharge aperture 501 is closed by button 502 formed on an inside of a flap 503 which is hingedly engaged to the housing through pivot axis 504. In use, the flap 503 may be rotated outwardly as shown in FIG. 31. The flap 503 supports two arms 505, 506 which act to hold a user's lips apart and provide entrance into the oral cavity after discharge from the aperture 501. A user may compress the resilient end 507 to operate an internal canister.

In FIG. 33, a further embodiment of a medical housing 550 is seen in which a slide cap may be removed by pulling it in the direction of arrow 552. The discharge

chute 553 may then move from a rotated position to a deployed position as seen in FIG. 33A and B. An air or oxygen line 554 provides inspiratory air to mix with the therapeutic agent. Preferably, the oxygen line discharges towards an outlet 555 of the chute 553. Alternatively or additionally, an air inlet aperture 556 may be provided in the chute 553. Further air inlets 557 may also be provided in the housing 550. A neck cord 559 may be provided to tie the housing around a user's neck or around a limb or anywhere suitable.

The present embodiment is particularly suitable for use with a frangible ampoule. FIG. 33B shows an ampoule 560 in position under a striker 561 designed to rupture the ampoule when brought into contact with it. Sliding of the cap 551 may compress the striker into operative position to rupture the ampoule and release the contents. The contents are preferably a volatile liquid such as methoxyflurane. The contents may then run down onto evaporative grid 563 which is designed to provide a large evaporation surface area. The grid may be formed by an absorbent open weave cloth fitted into position in the housing 550. Alternatively, the grid may be formed from a number of polymeric vanes locked together to form an effective evaporating arrangement.

10

20

A user may commence breathing after rupturing the ampoule and, once used to the sensation of the medication, may occlude the aperture 556 to increase concentration of the agent in the airstream. Of course, there are many volatile agents which may be suitable for use in the present arrangement.

A further view of a similar arrangement is shown in FIG. 34 where the housing 600 has a chute 601 which rotates into and out of position. A striker 602 is positioned to rupture frangible ampoule 603 and discharge the contents onto the

evaporation grid 604. In this embodiment, an inlet one-way valve 605 is provided to prevent loss of the volatile material through the housing. It is also envisaged that the valve would cause air to flow in a preferred direction possibly out of the aperture 607 which may be connected to an enclosed piping channel to direct the discharge air to a scavenger system or to an absorbent system such as charcoal filter. This arrangement prevents or minimises contamination of the local environment with potentially hazardous or explosive materials in a potentially hazardous situation. This enhances safety for surrounding health workers, particularly when in a confined circumstance such as in an ambulance or hospital cubicle. An example is shown in FIG. 38 where a housing 800 contains an ampoule 801 and evaporation grid 802. Removal of outer cap 803 allows rotation of outlet chute 804 with attached absorber 805. Air is inhaled through pathway 806 and exhaled through expiratory pathway 807 through the absorber 805. Two one-way valves 808, 809 allow air inflow and one one-way valve 810 permits outflow.

10

20

FIGS. 35, 36 and 37 show a mechanism in a housing 700 for counting or at least indicating the number of times a medical canister has been discharged thereby providing a user with an indication of the remaining level of therapeutic agent in the device. Referring to FIG. 35B which is an exploded view, there is an end cap 701 and barrel 702. The end cap has a number of resilient claws 703 which interlock with apertured tabs 704 to fix the end cap 701 in position relative to the barrel 702 and prevent relative movement therebetween. The end cap may be removed if required to replace a medication canister or may be locked to prevent reuse. The interlocking arrangement is seen in FIG. 35A. The end cap 701 has one or more tongues 706 adapted to locate in a recess 707 of an internal band 708 positioned inside the barrel. The band 708 supports a

flexible finger 709 that terminates in a tooth dimensioned to insert in any one of a number of continuous serrations 710.

Referring to FIG. 36, it can be seen that depression of the end cap 701 causes the tongue 706 which is formed at an angle to urge the band 708 in the direction of arrow 711. This causes the finger 709 to lock into its serration and move the threaded cylinder 712 also in the direction of arrow 711.

Release of the end cap 701 causes it to return to its original position. The presence of tabs 713 prevents rotational movement of the end cap 701 as they mate with corresponding slots in the barrel. As the end cap rises, it pushes the band 708 in the reverse direction to arrow 711 causing the finger to roll over its serration or cammed surface and into the next recess ready for a subsequent use. The external thread 714 cooperates with a corresponding thread 715 which co-operates with an indicator mounted in inspection window 716. With rotation of the threaded cylinder 714, the indicator is advanced across a scale which provides an indication of the level of medication in the canister. The scale may be any suitable range of indicia. In a preferred embodiment, the scale is two or more colours ranging preferably from green for full or almost full through yellow for when the canister is around half full to red indicating the canister should not be used. It is preferred to provide the red colouration when there is still a wide safety margin in the amount of material left in the canister. Any suitable array may be used as an indicator of the canister's suitability for use. The present arrangement may be used for a single canister medication housing which is disposable once the indicator system flags a potential shortage of medication. Alternatively, the present arrangement may be adapted for resetting of the indicator window with subsequent insertion of a new medical canister.

10

15

A stop 720 is provided on the cylinder 712. The stop 720 is formed to cooperate with serrations 721 to prevent the cylinder 712 reversing its direction of rotation. That is, the stop allows rotation in a first direction to wind the indicator up but resists operation of the finger 709 from causing the cylinder to rotate backwards.

Throughout the specification, the aim has been to describe the preferred embodiments of the invention without limiting the invention to any one embodiment or specific collection of features. Those of skill in the art will therefore appreciate that, in light of the instant disclosure, various modifications and changes can be made in the particular embodiments exemplified without departing from the scope of the present invention. All such modifications and changes are intended to be included within the scope of the above disclosure.

DATED this twenty-sixth day of March 2004.

DAVID WHARTON

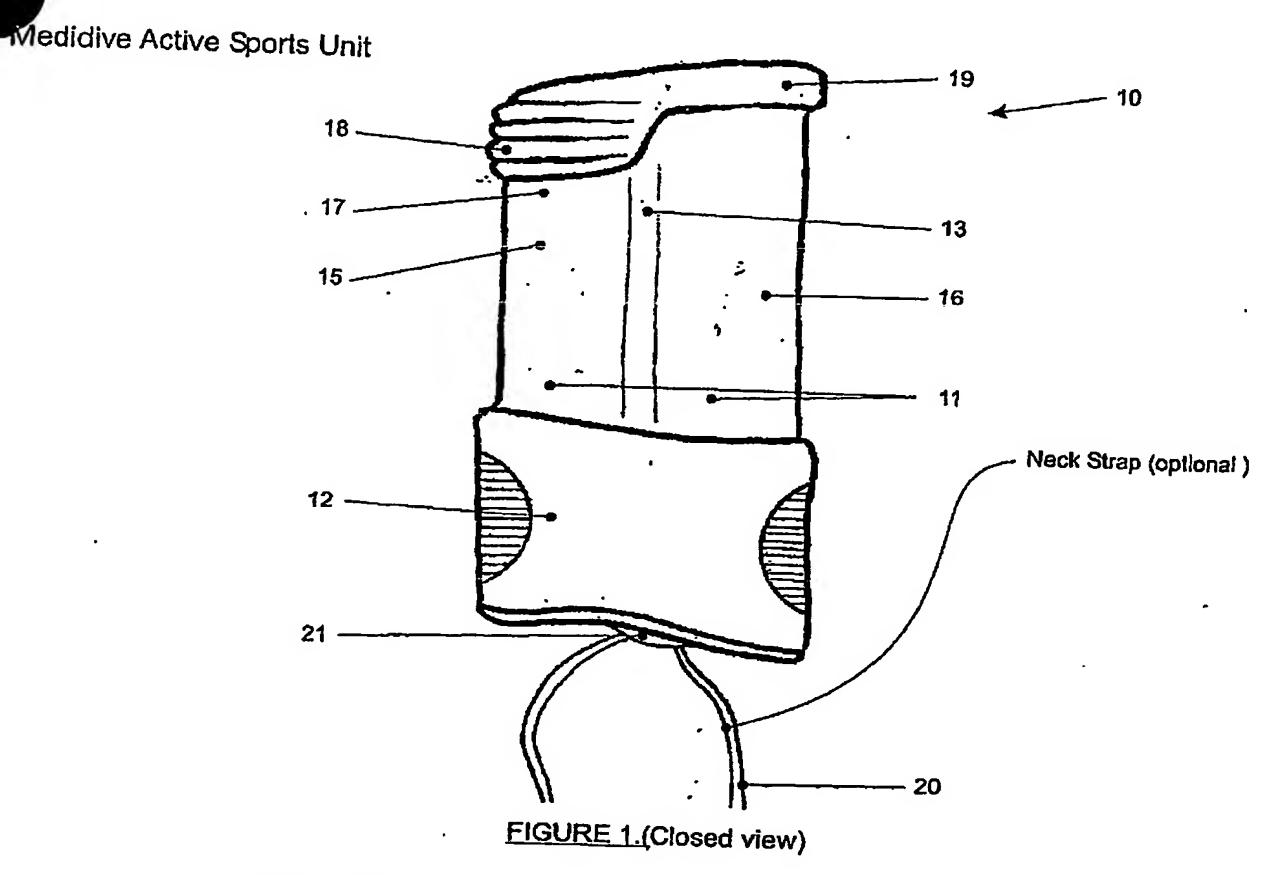
By DAVIES COLLISON CAVE

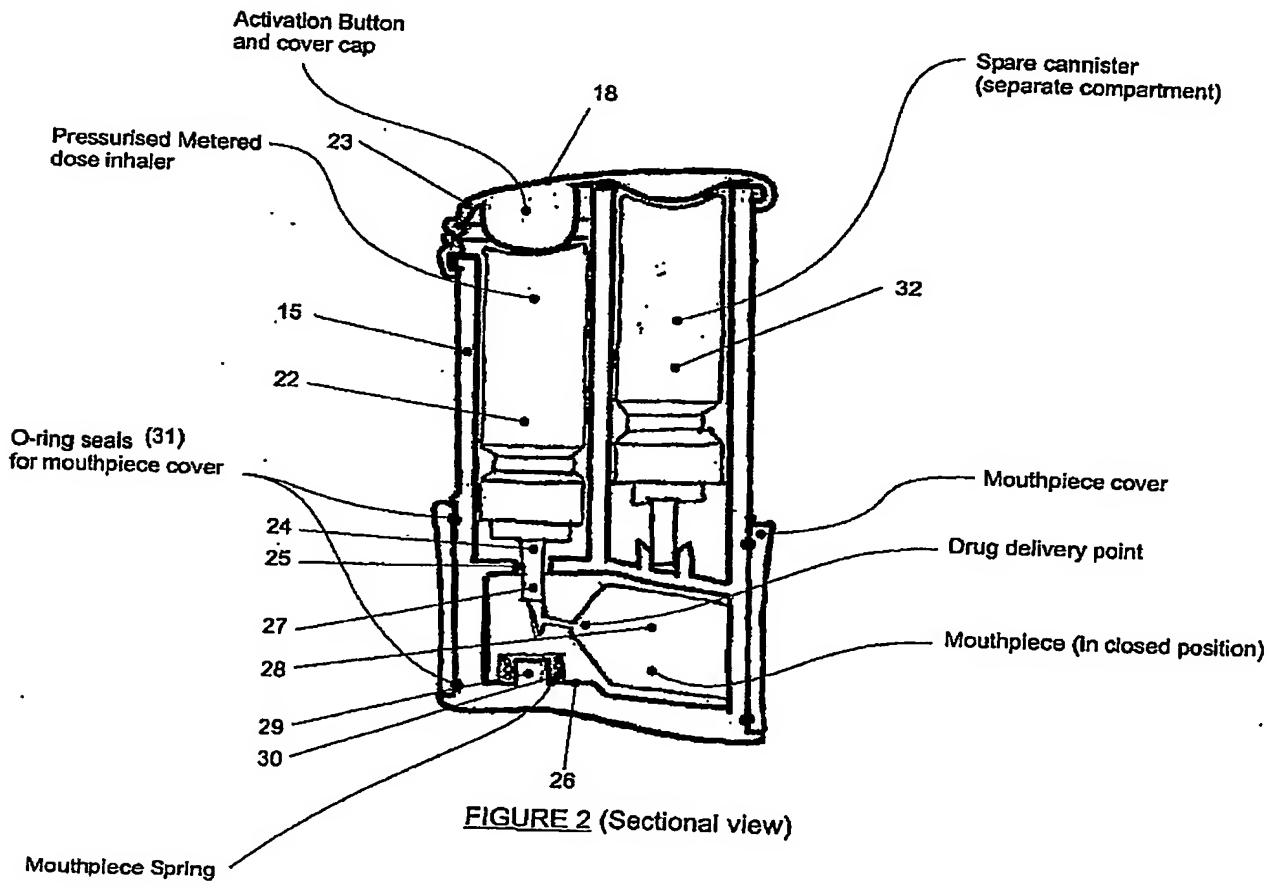
Patent Attorneys for the Applicant

15

10

5





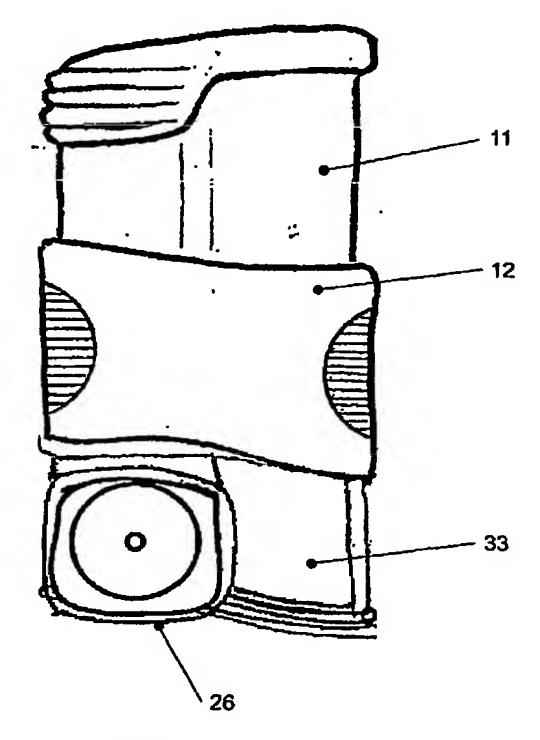


FIGURE 3.



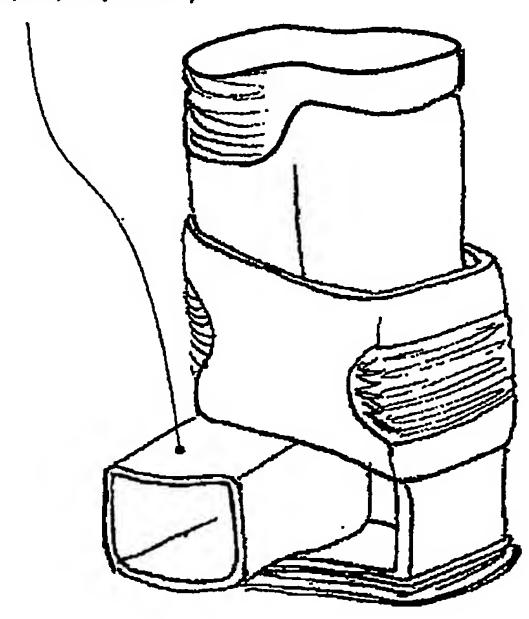


FIGURE 4.

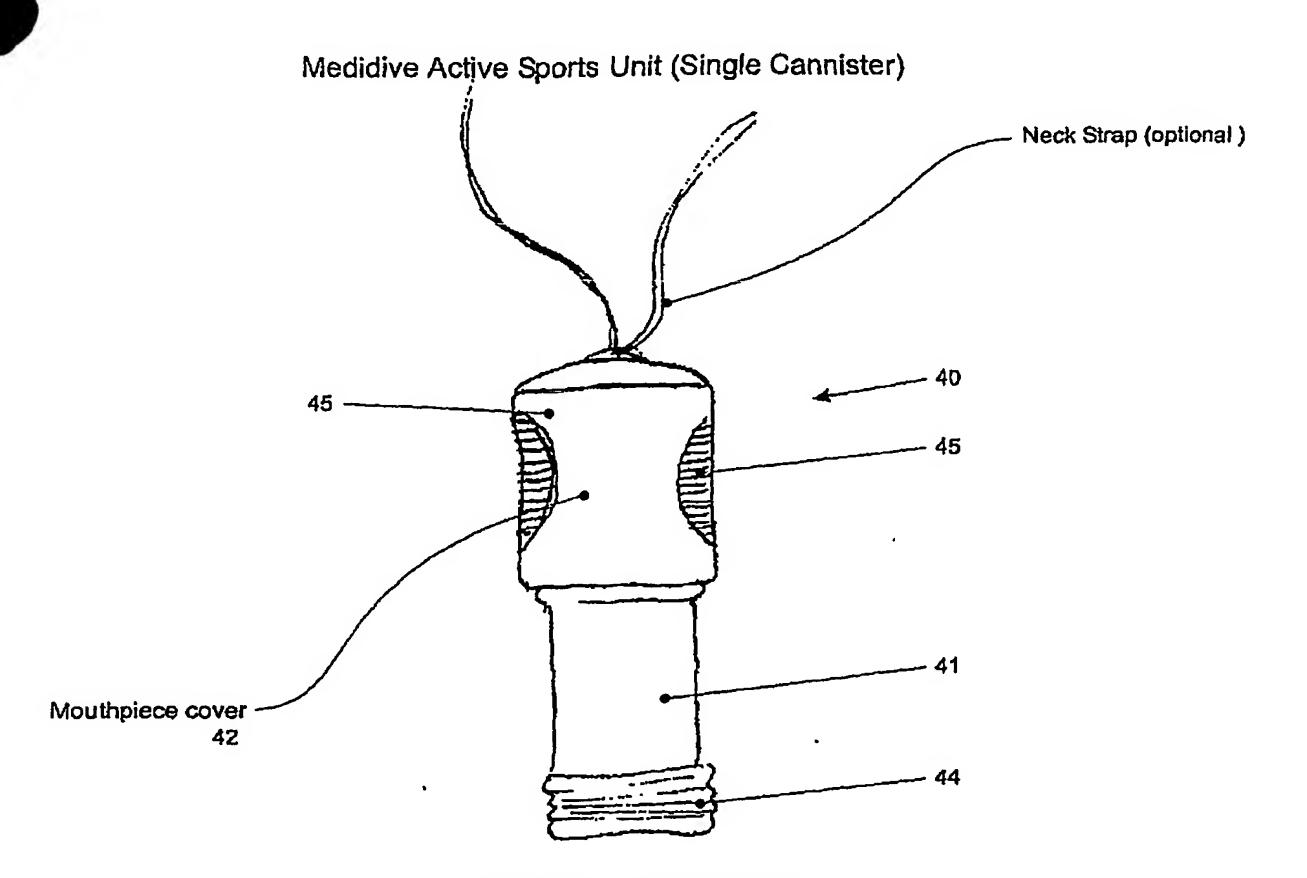
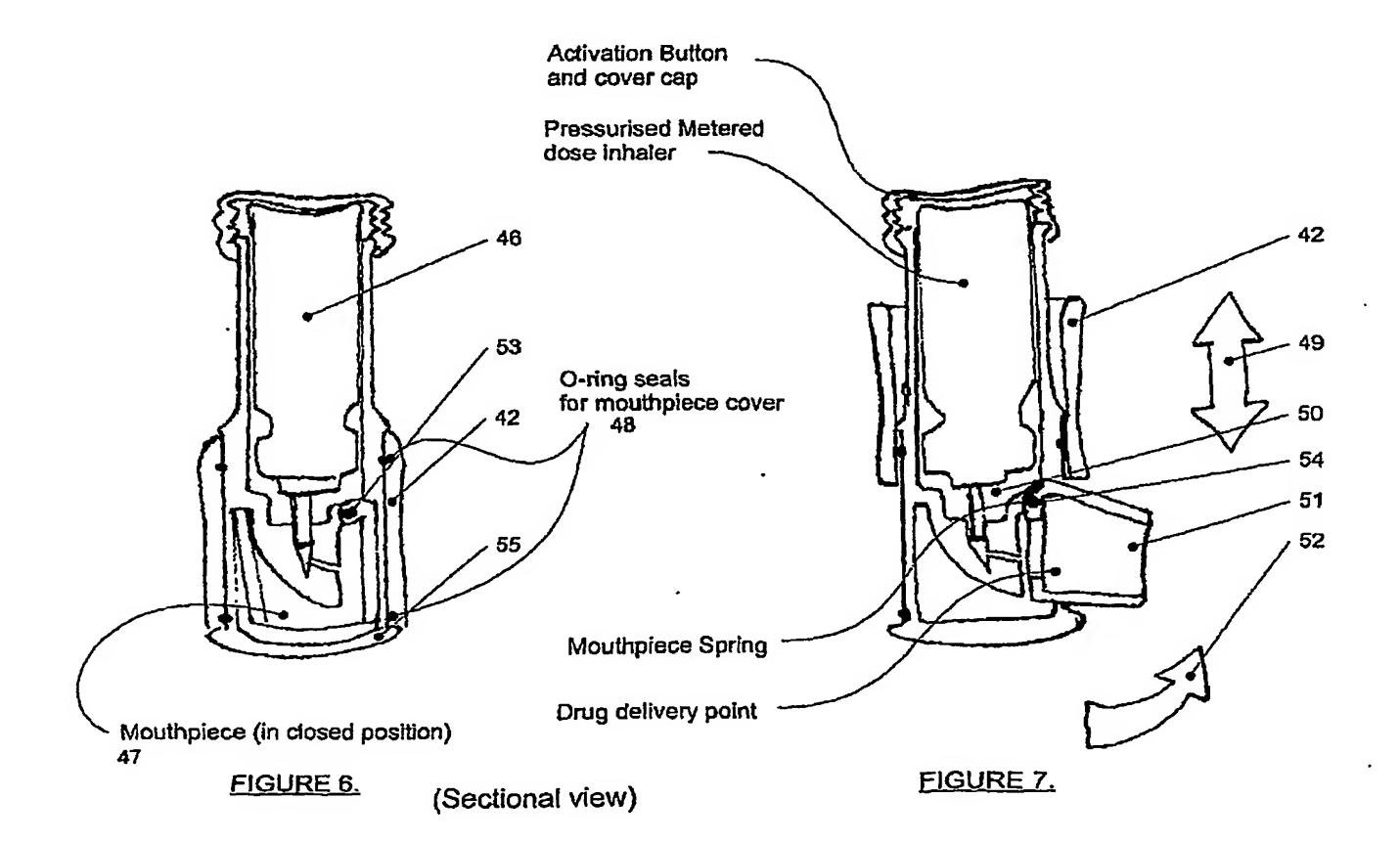
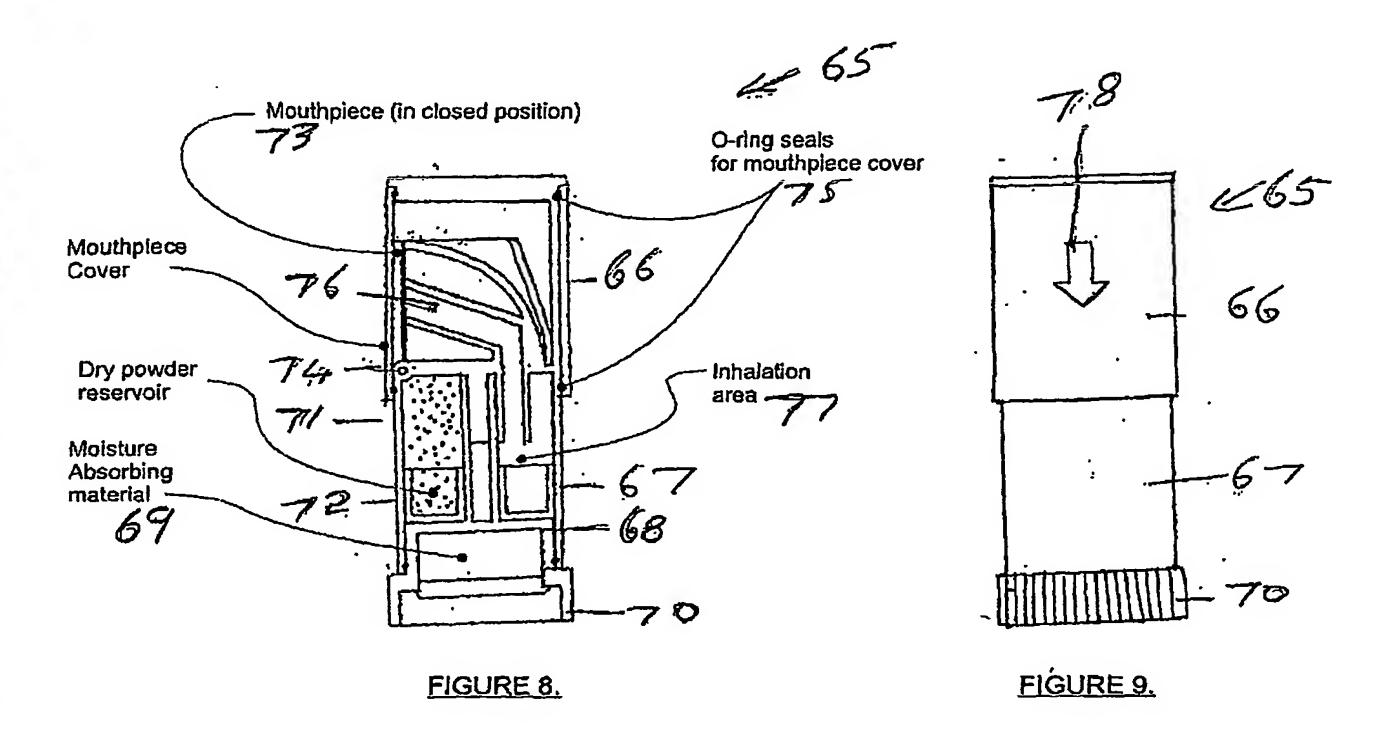
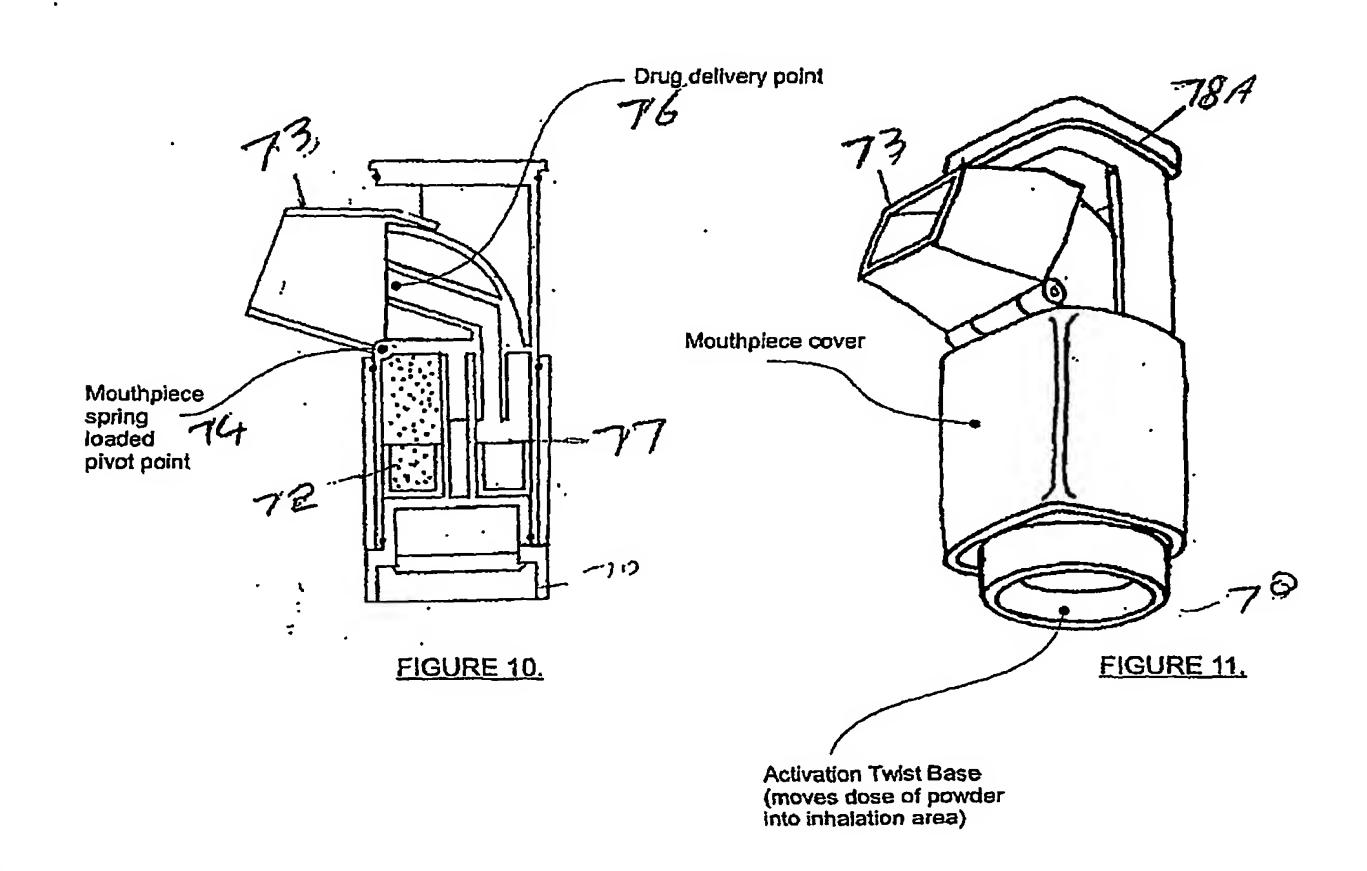


FIGURE 5. (Closed view)

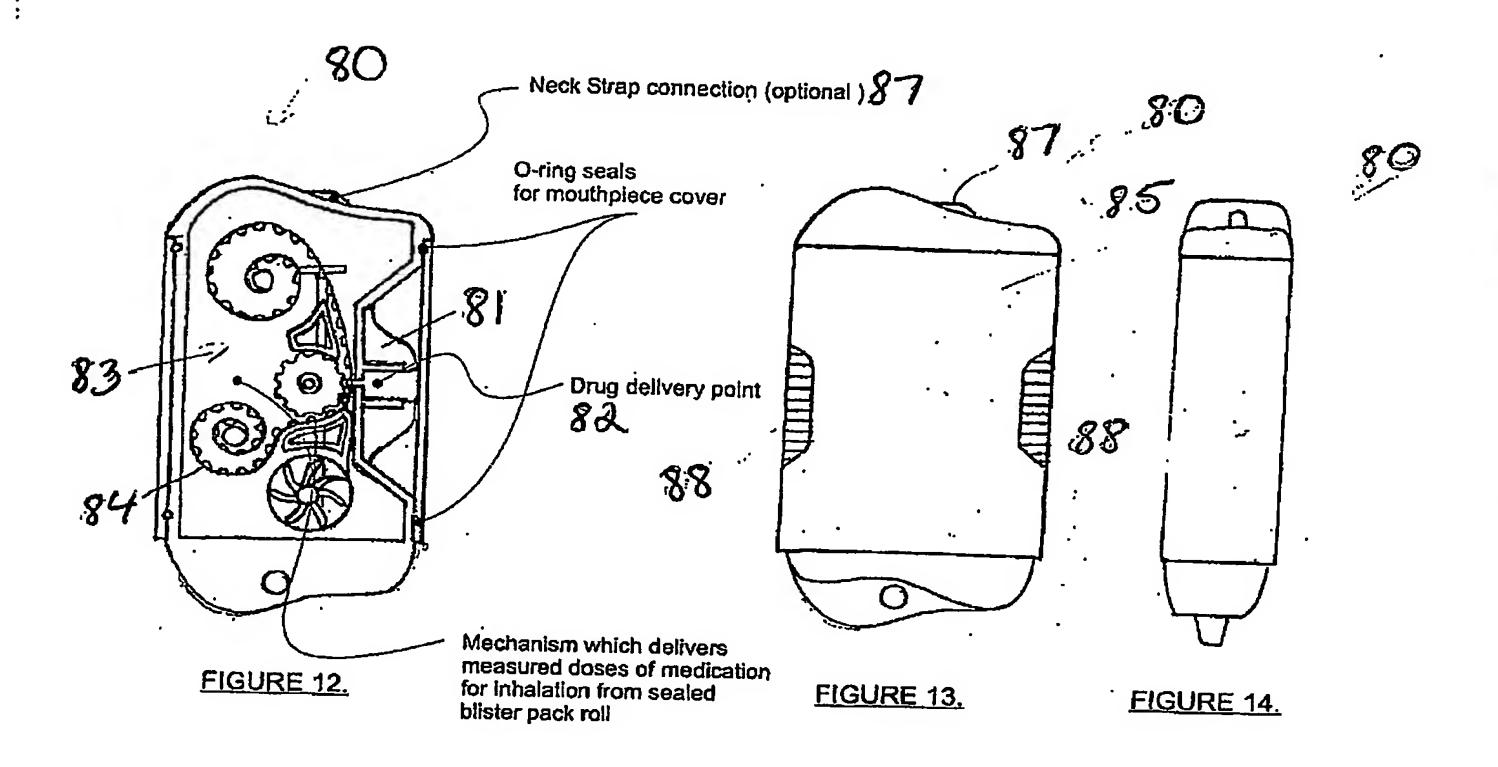


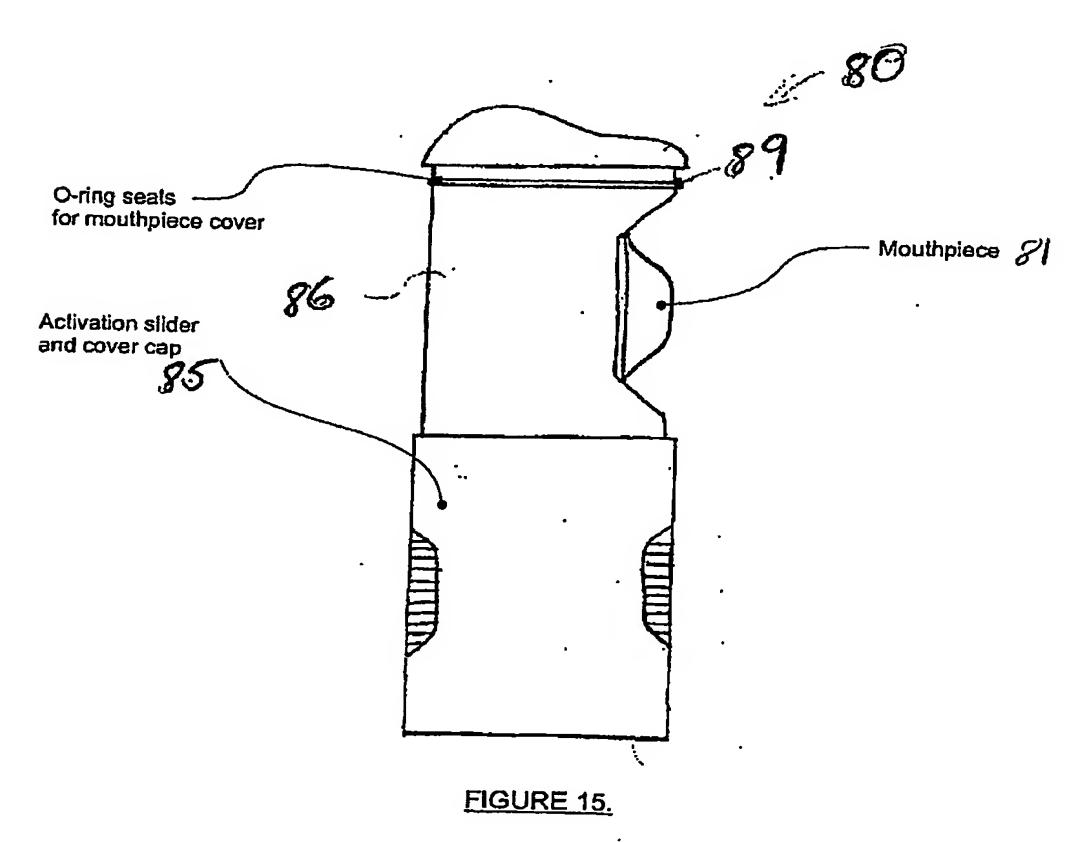
## Medidive Active Sports Unit (Dry Powder Inhaler)

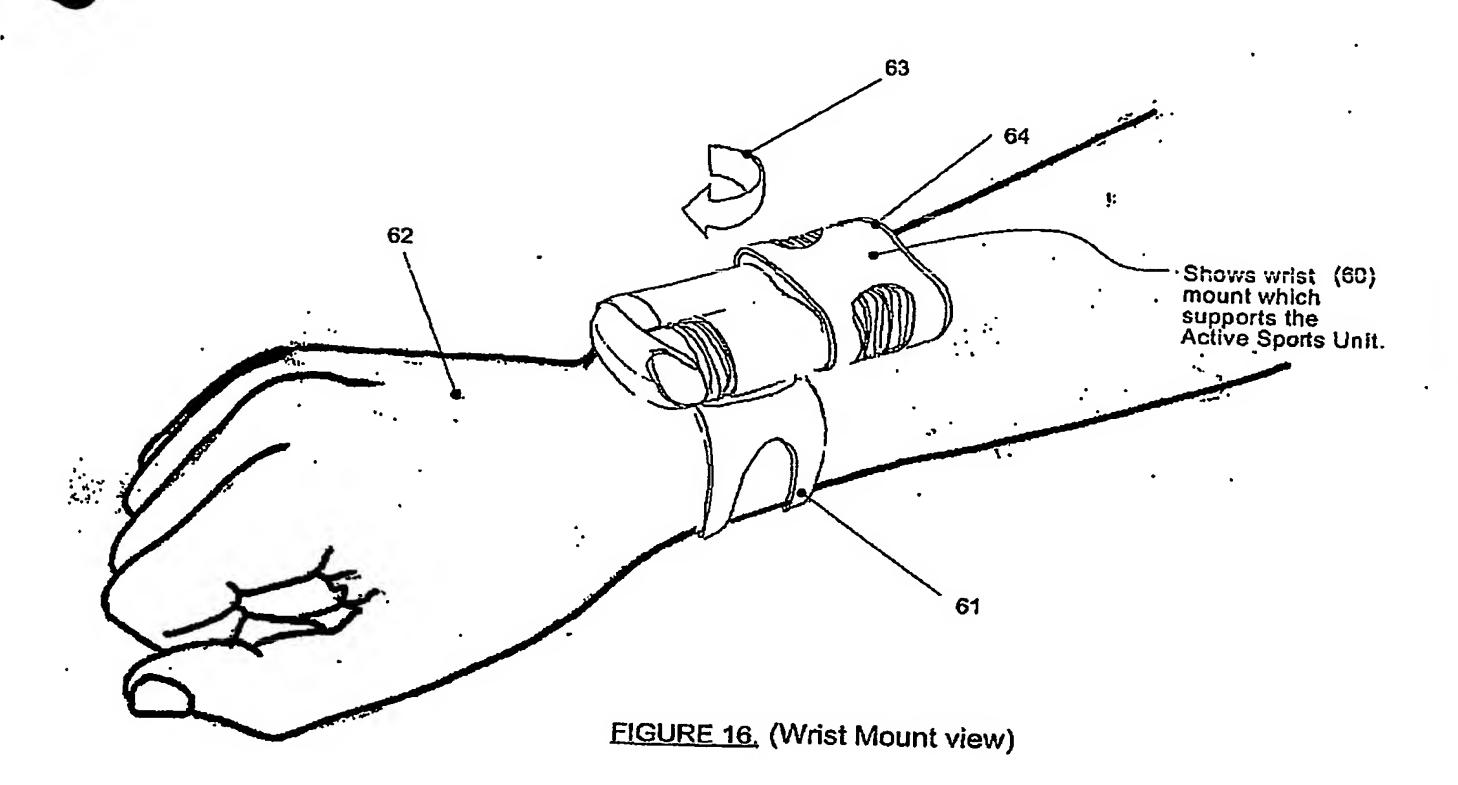


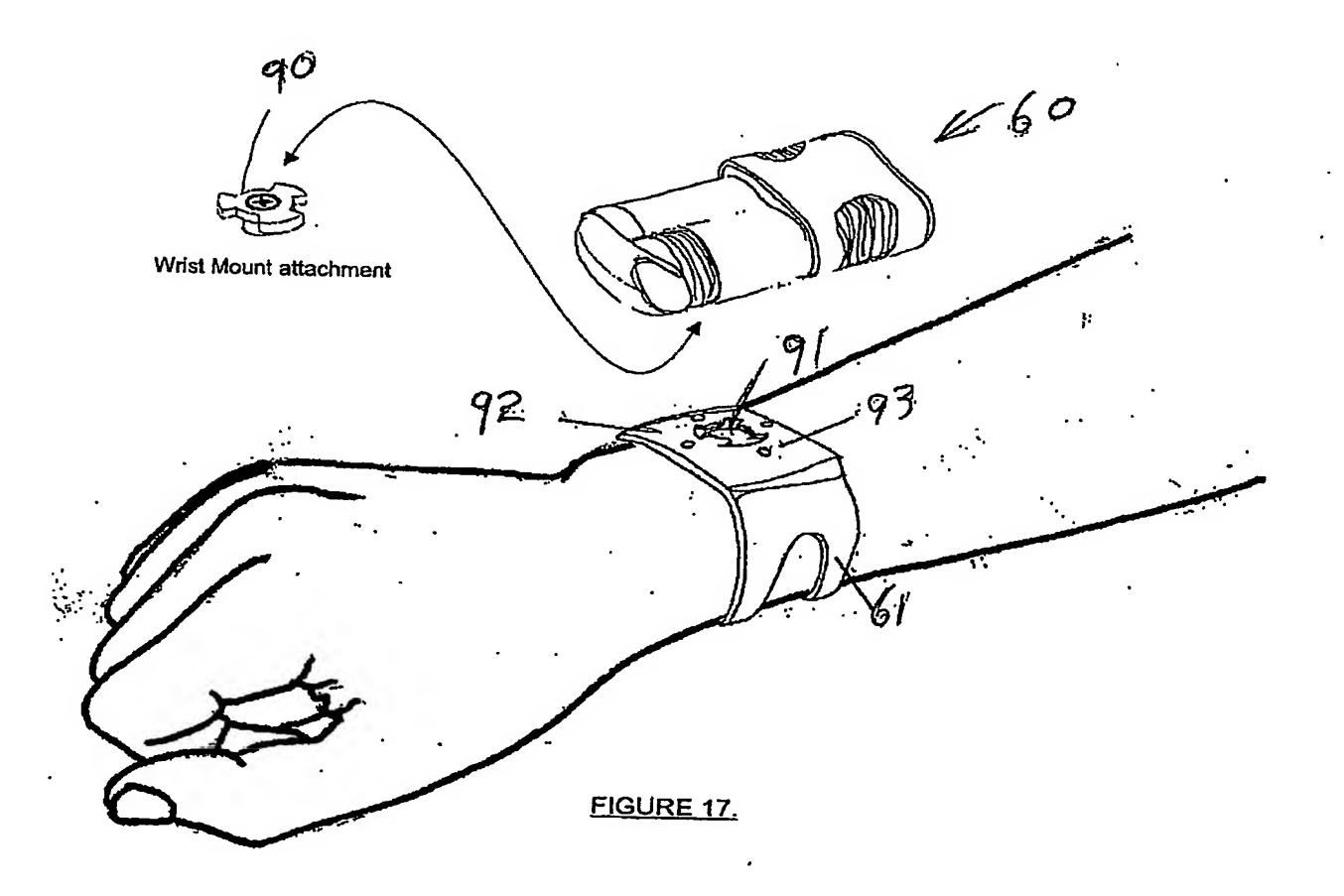


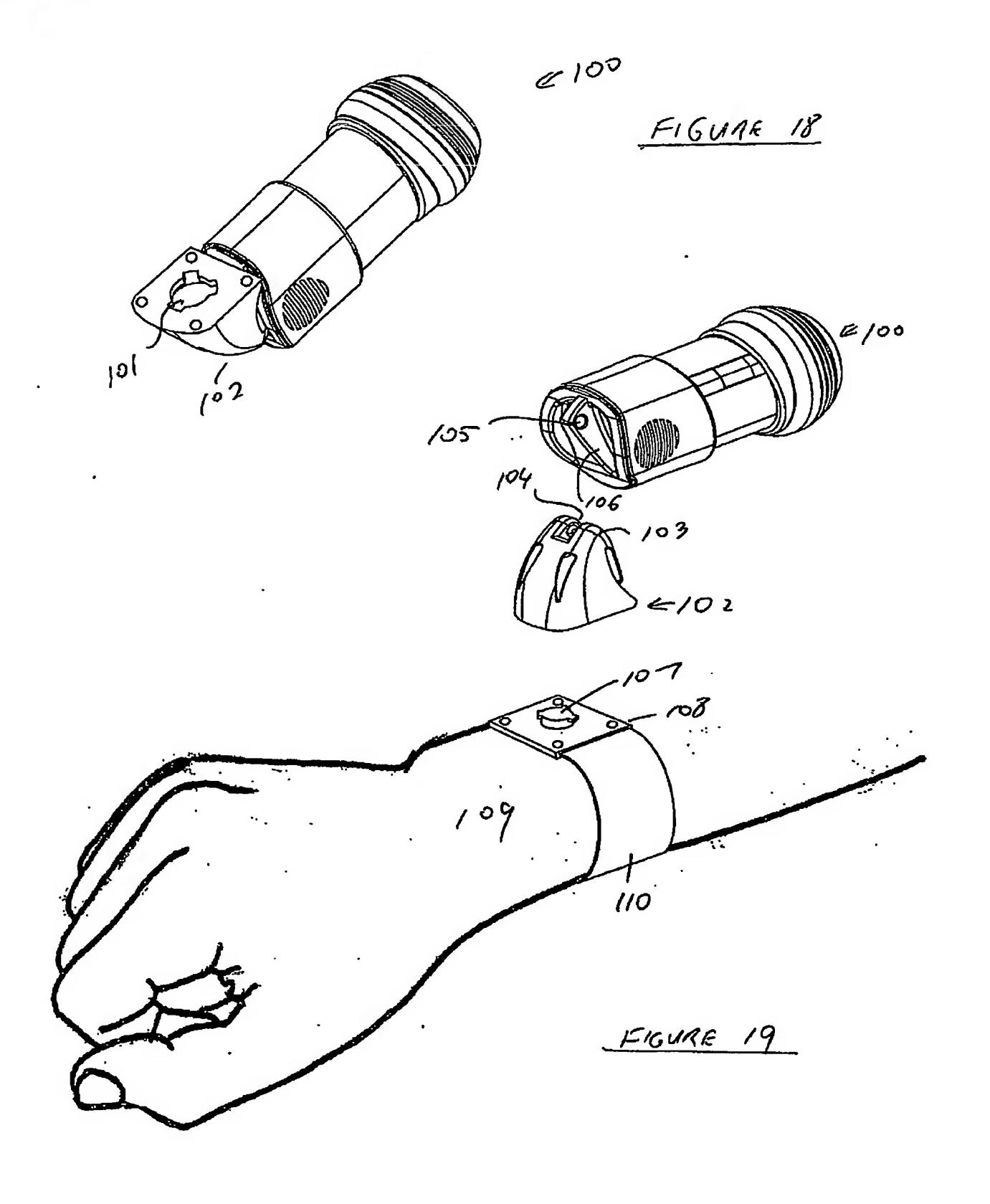
## Medidive Active Sports Unit (Dry Powder Capsules)

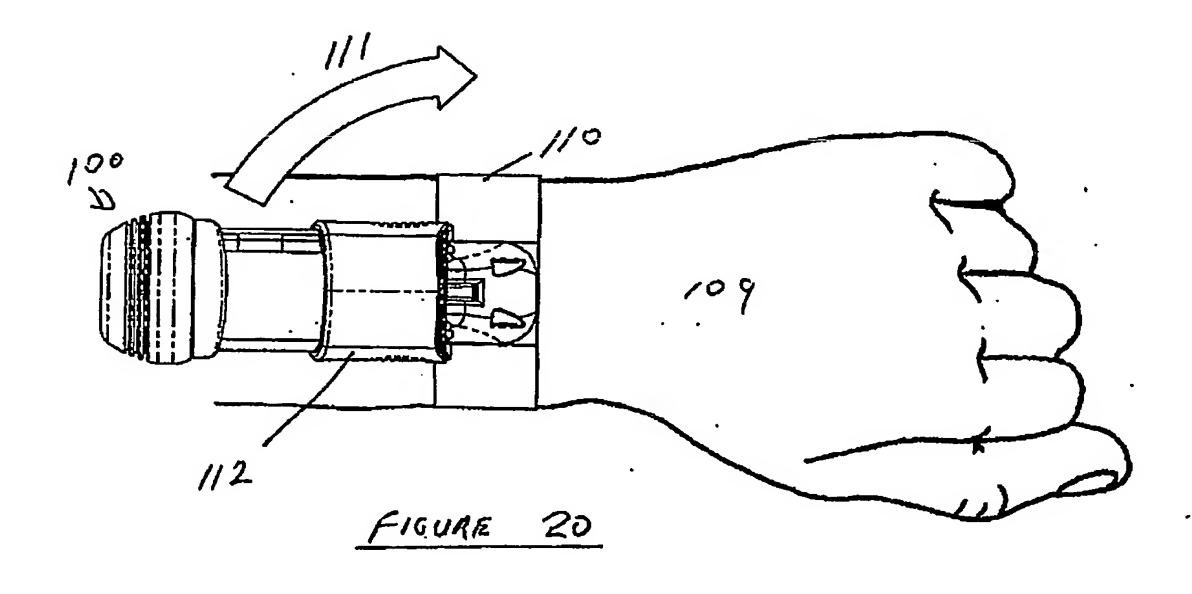


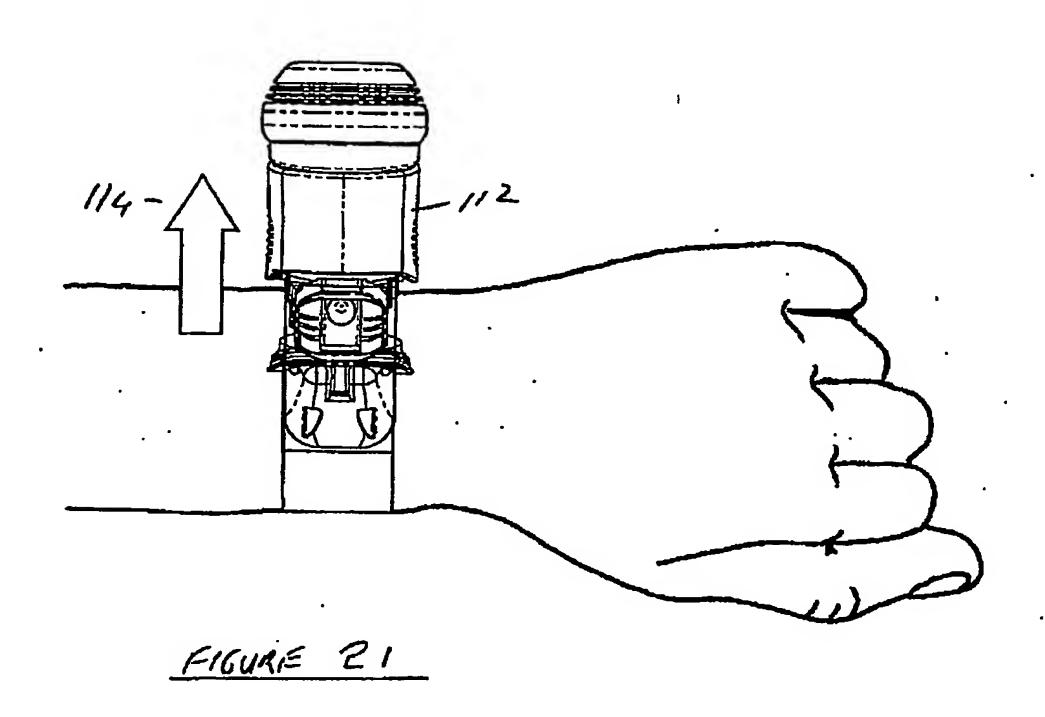












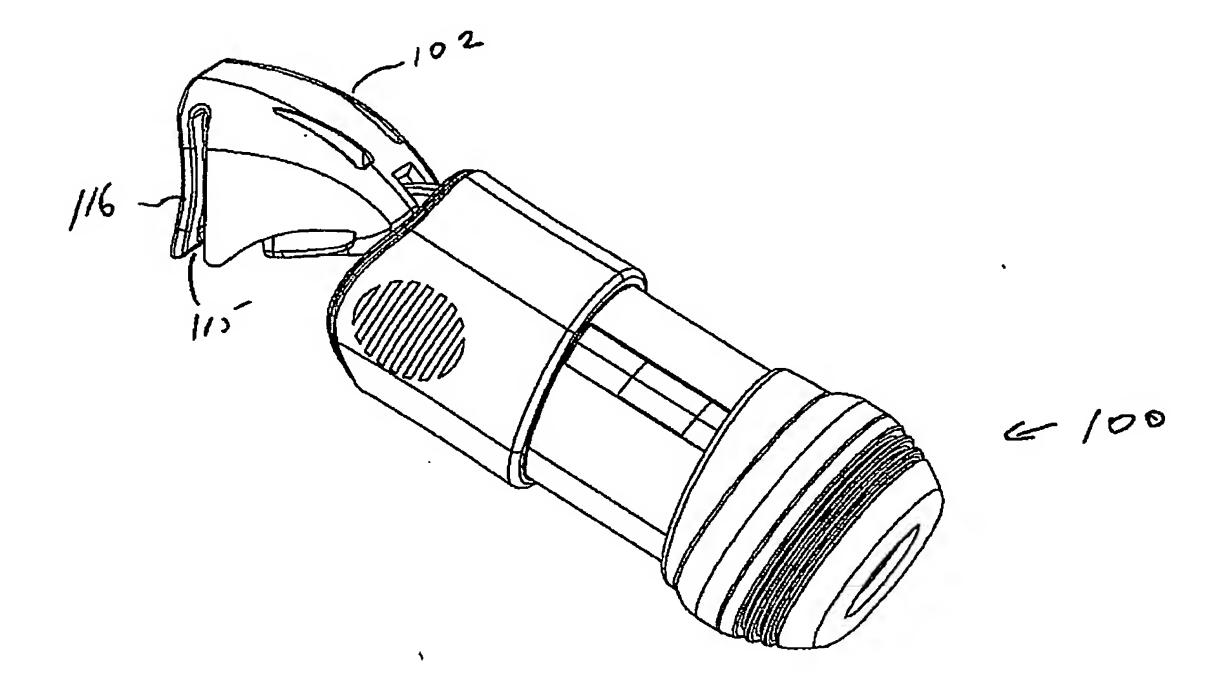
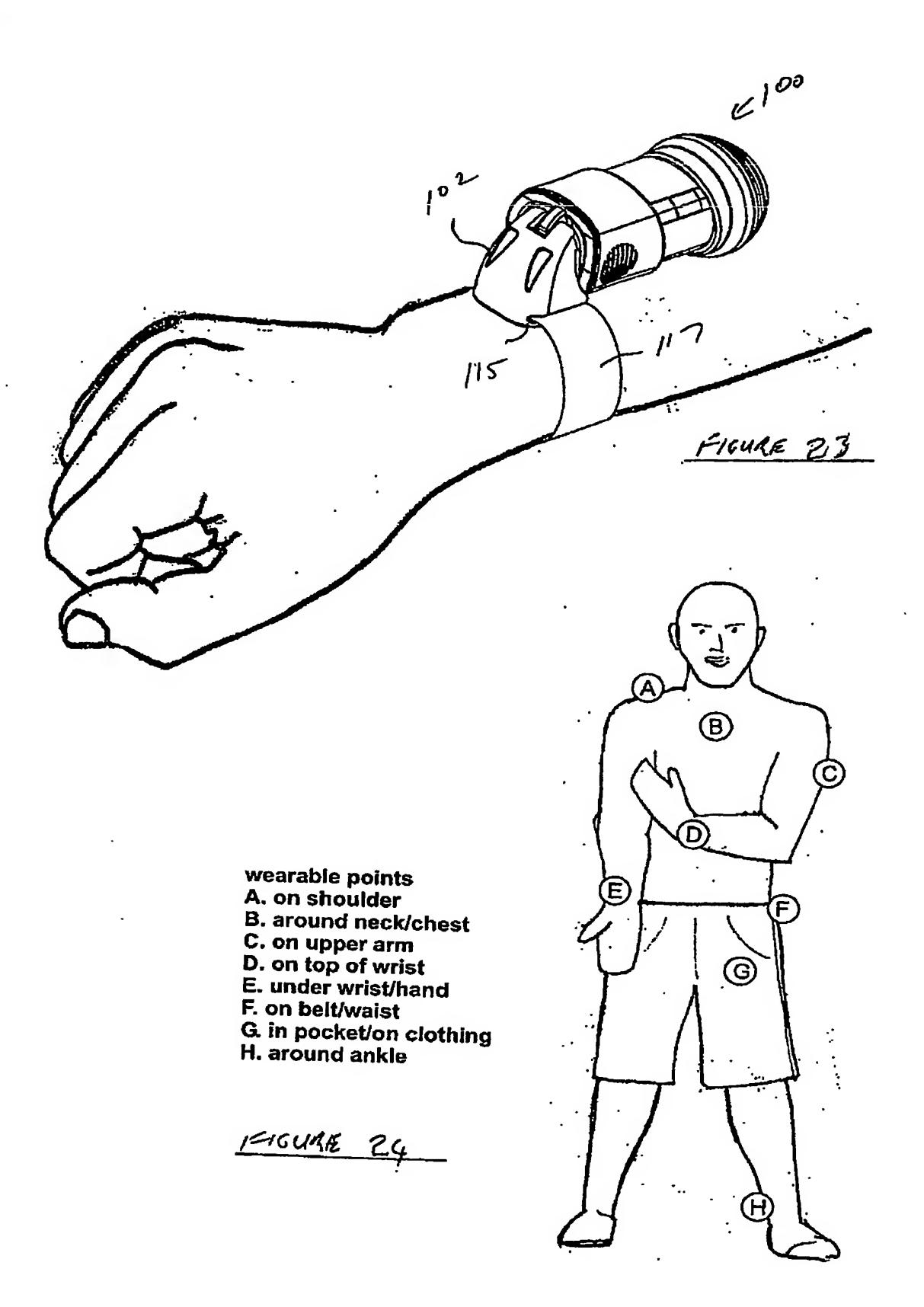
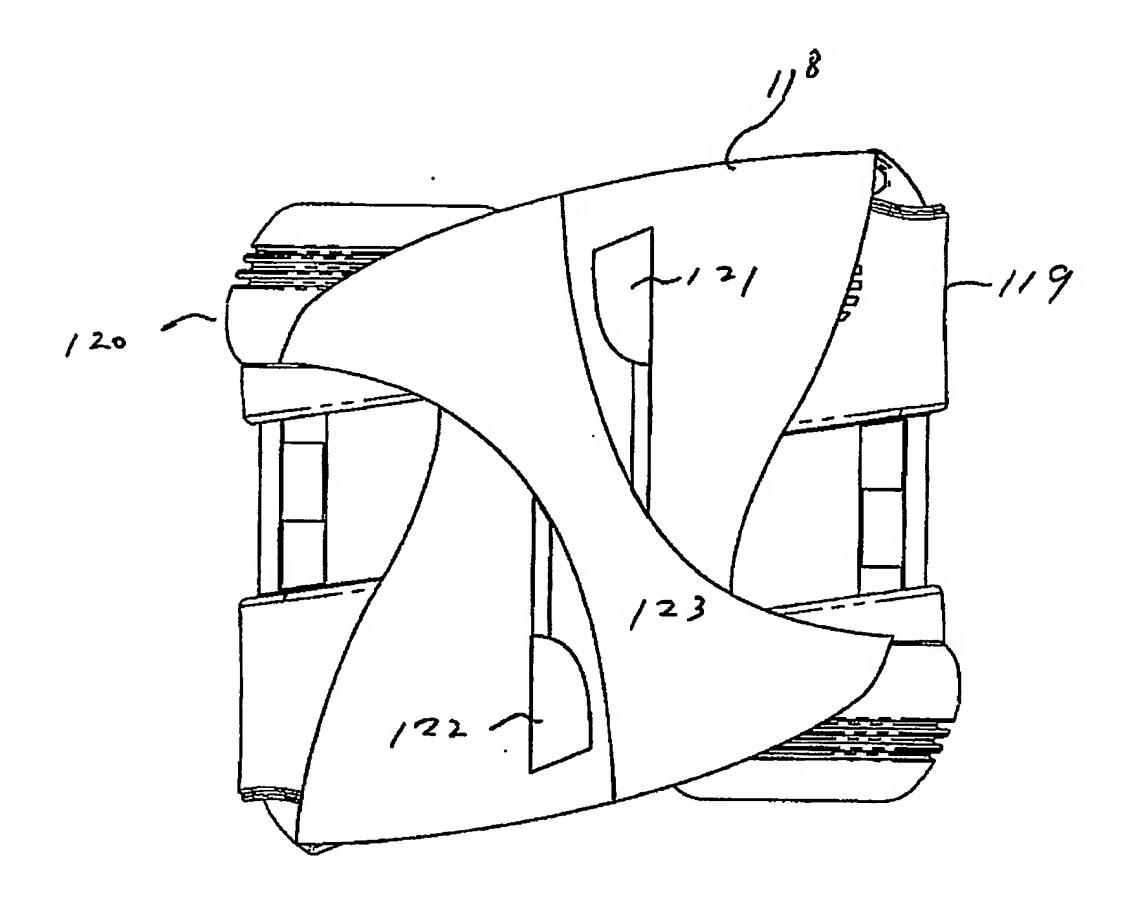
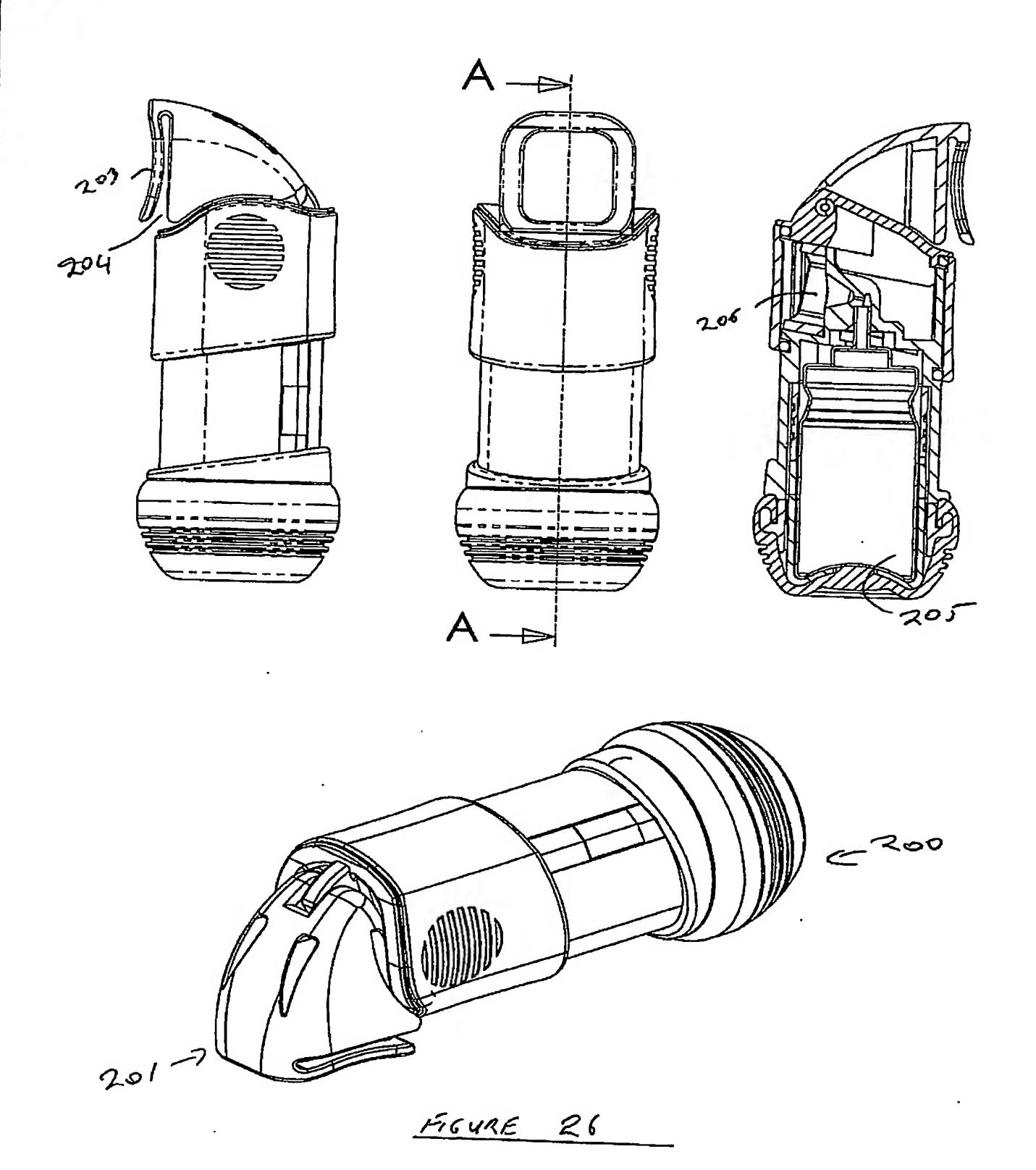


FIGURE 22





F-16UAE 25



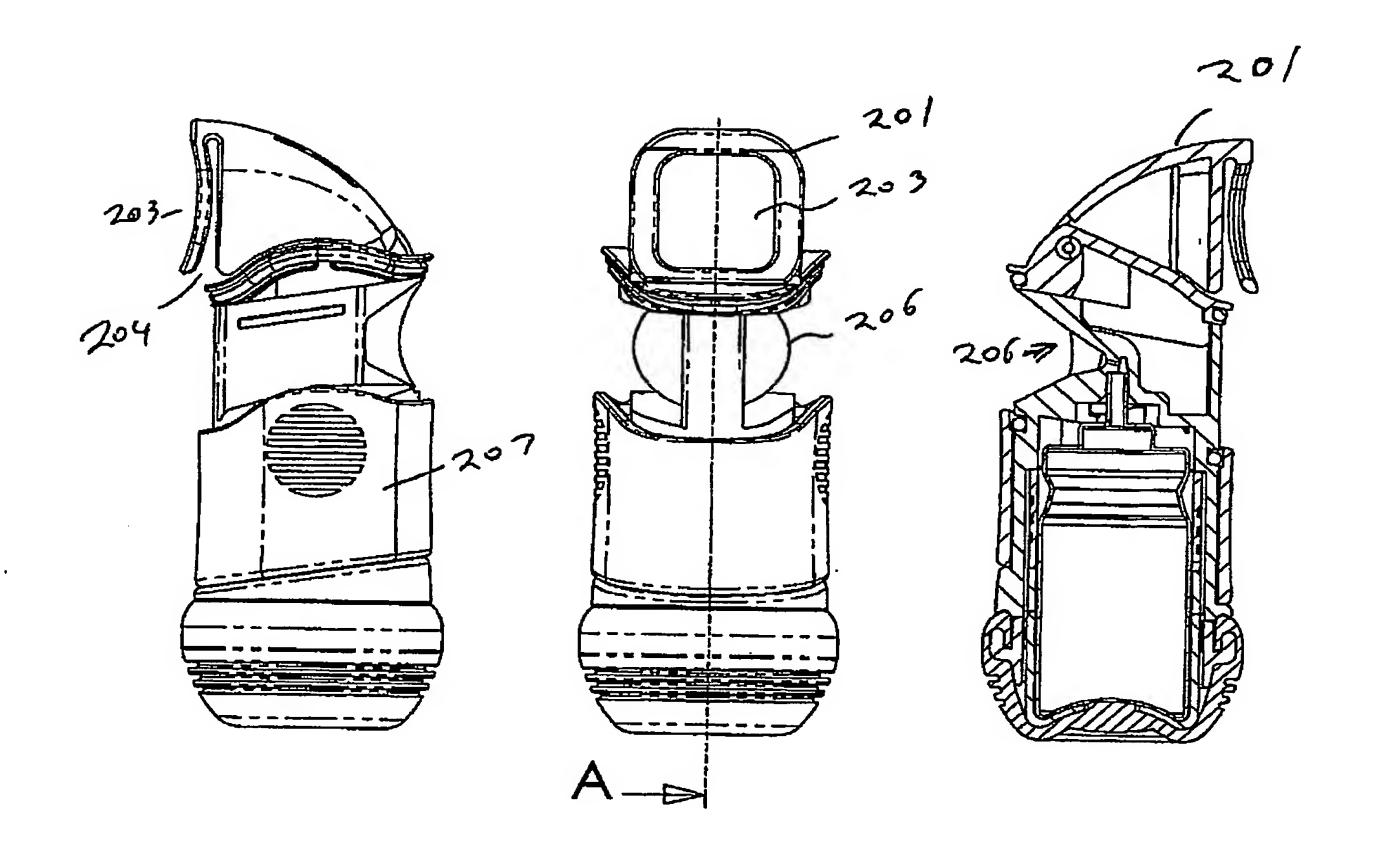
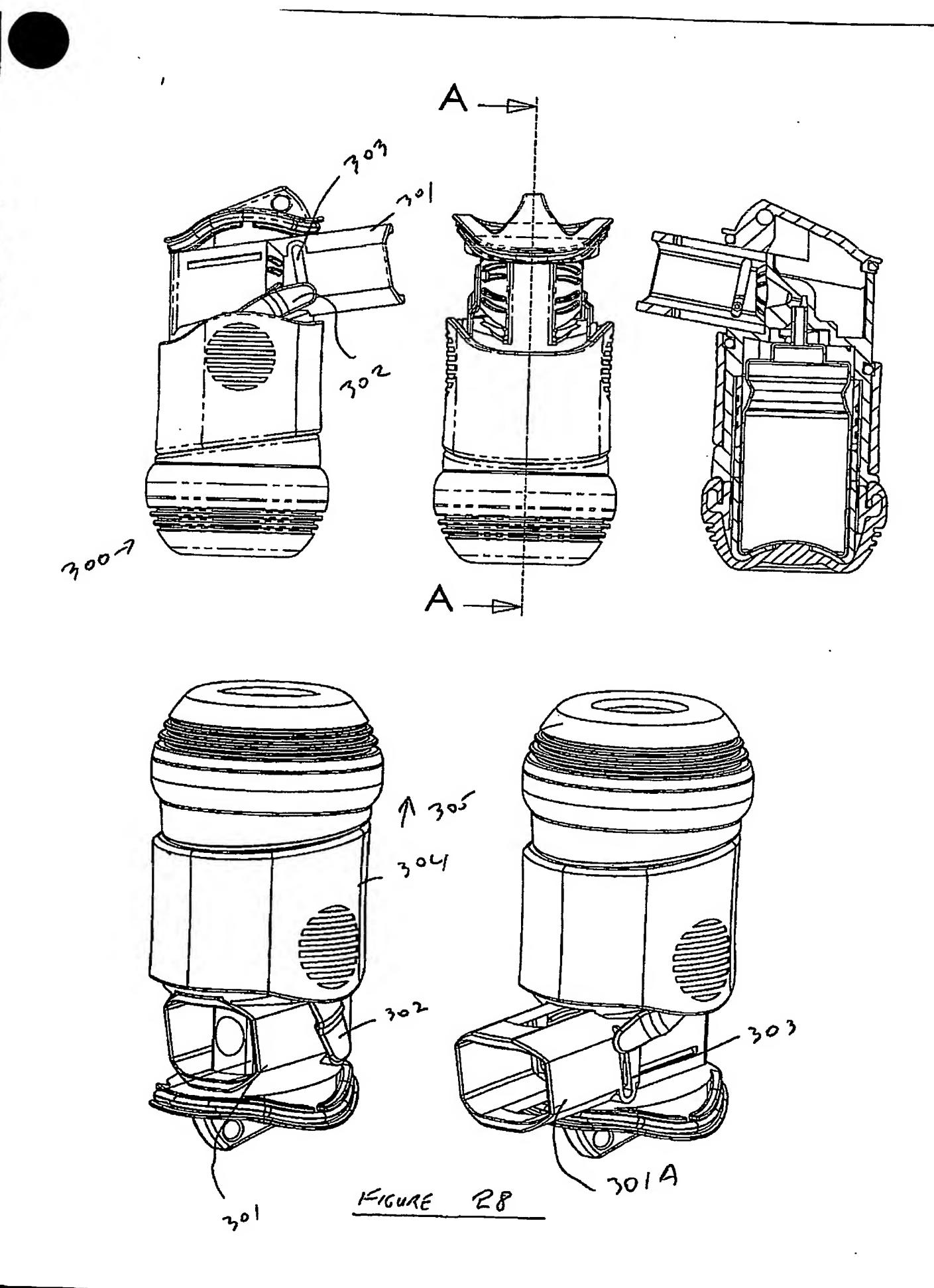
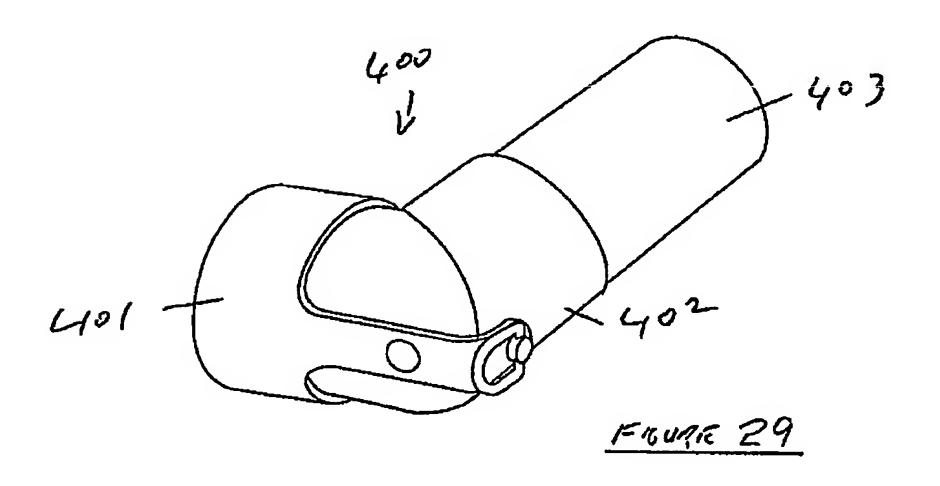
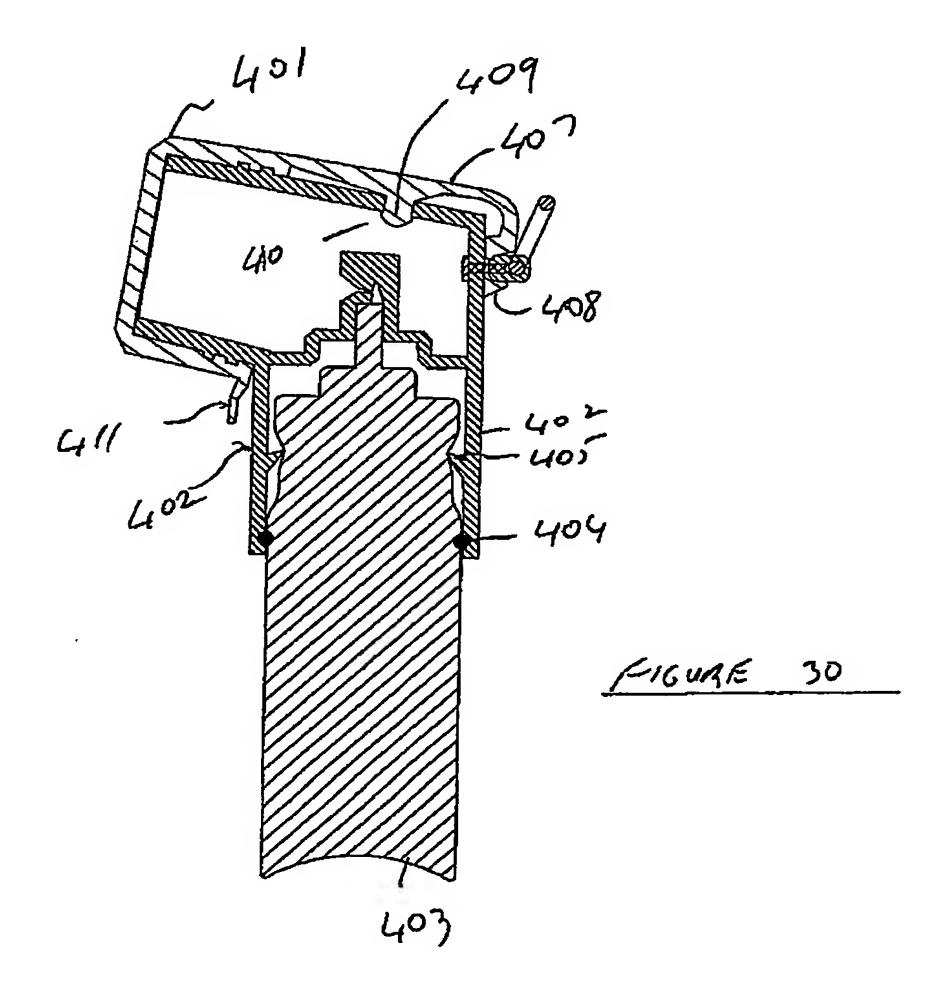
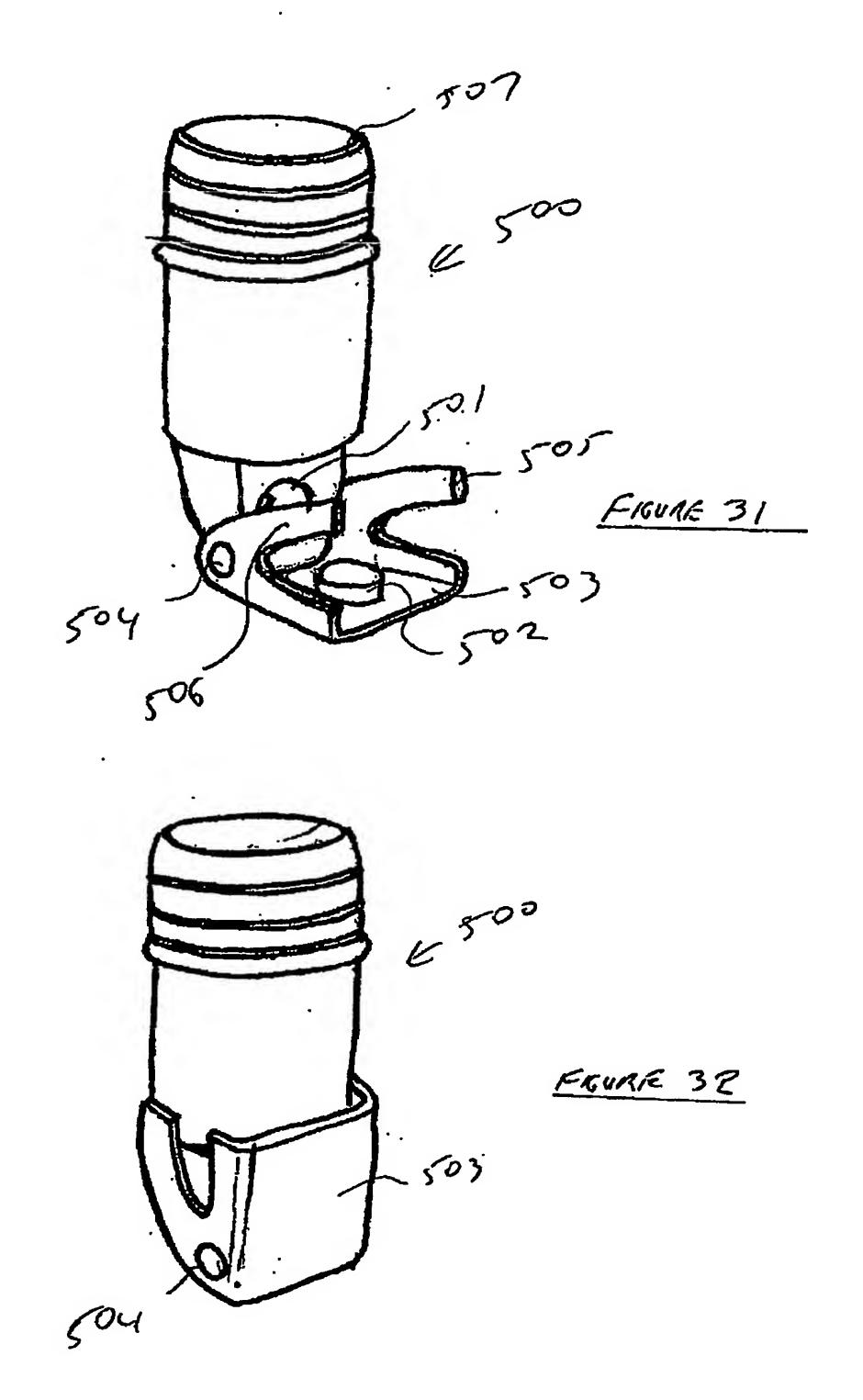


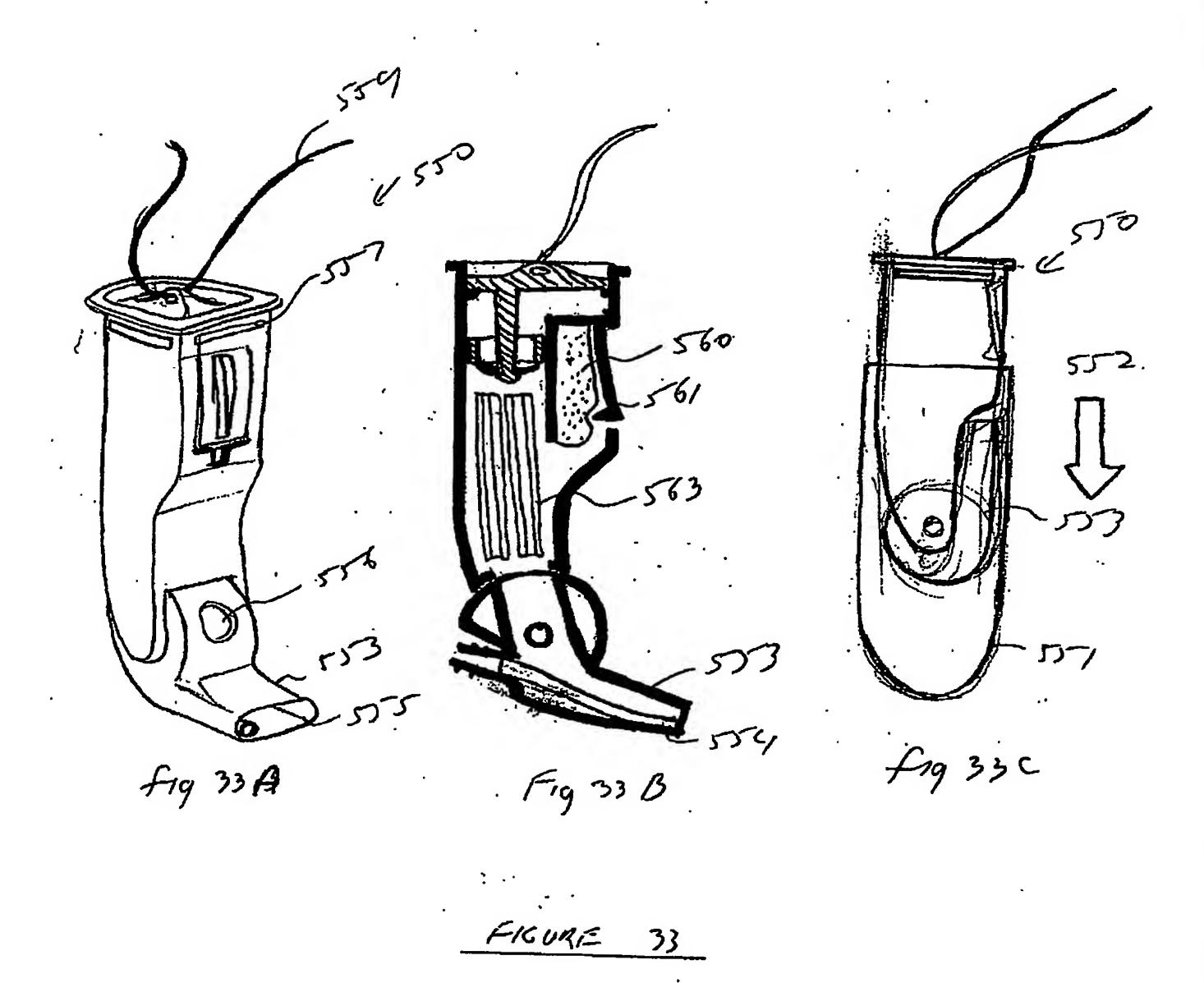
FIGURE 27

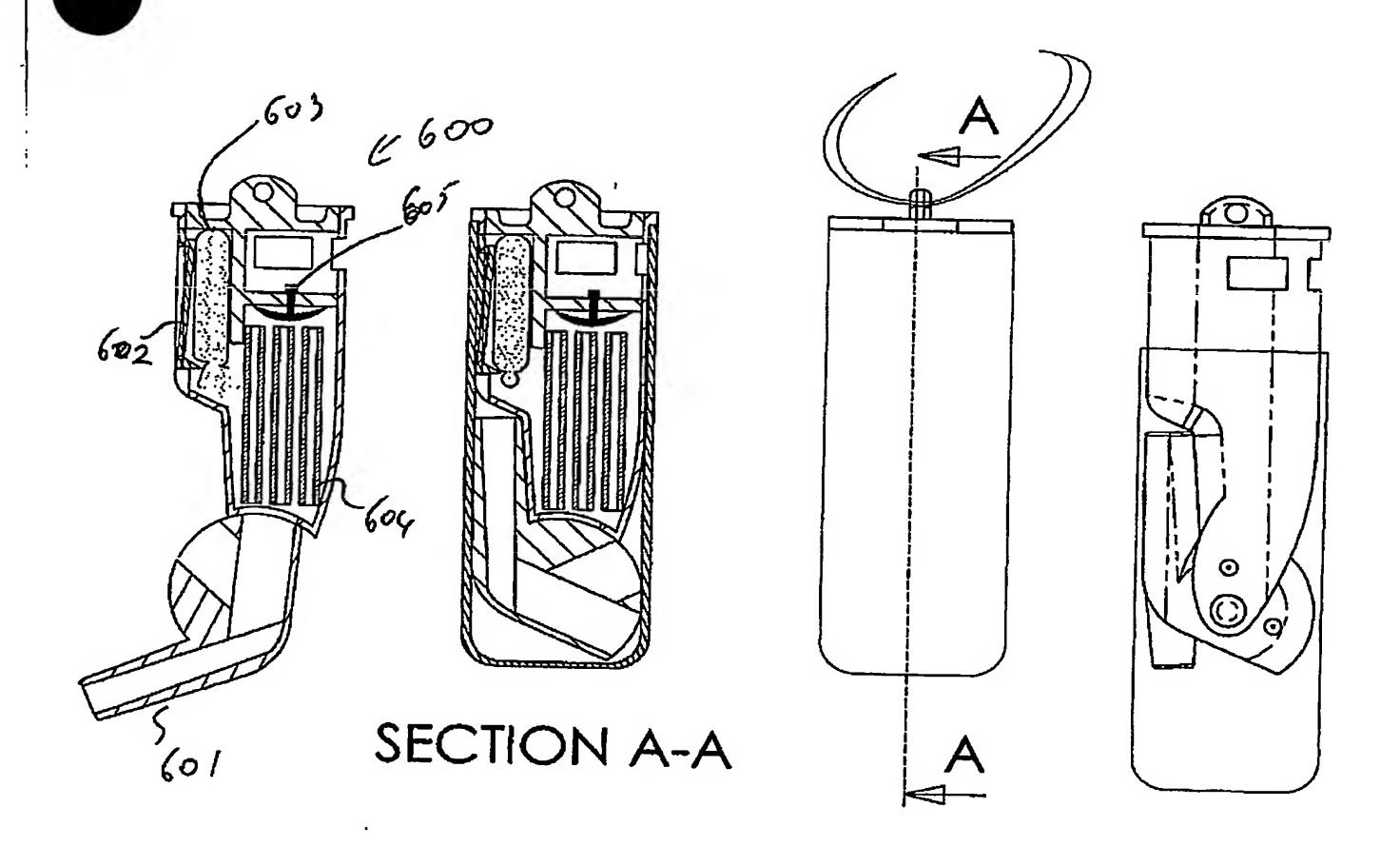


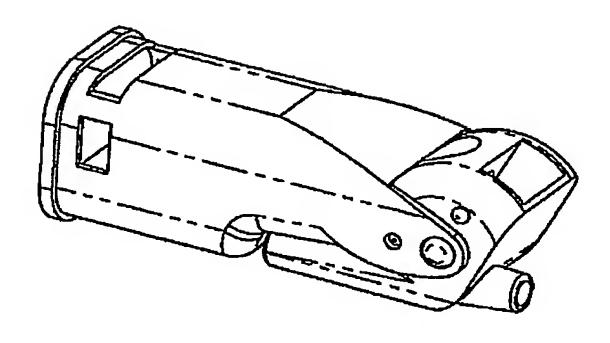












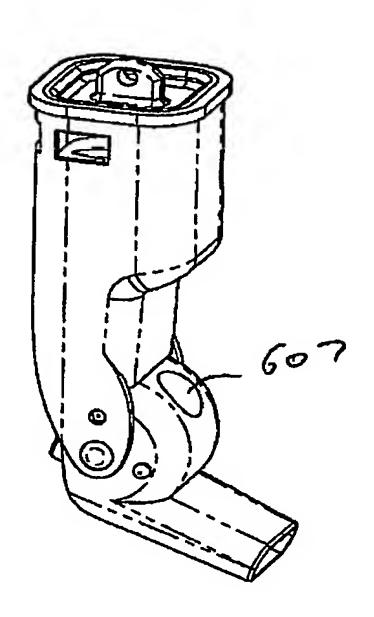
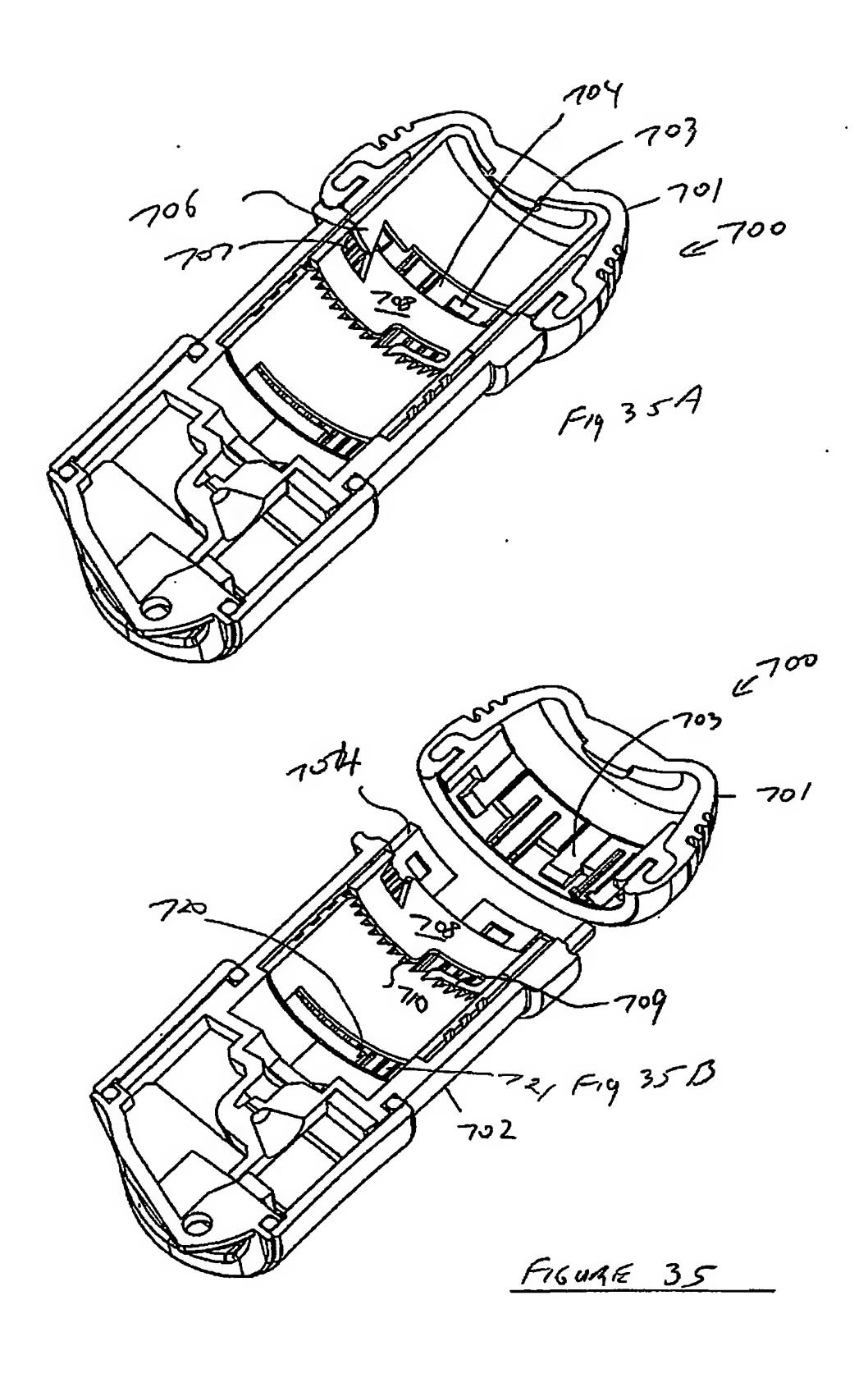
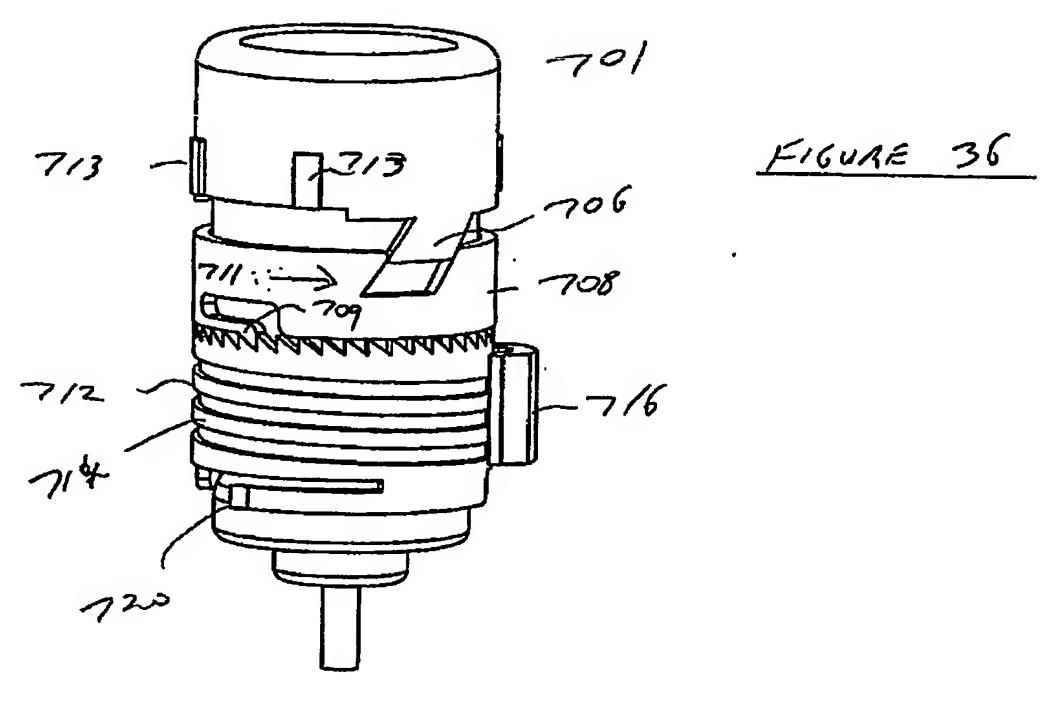


FIGURE 34





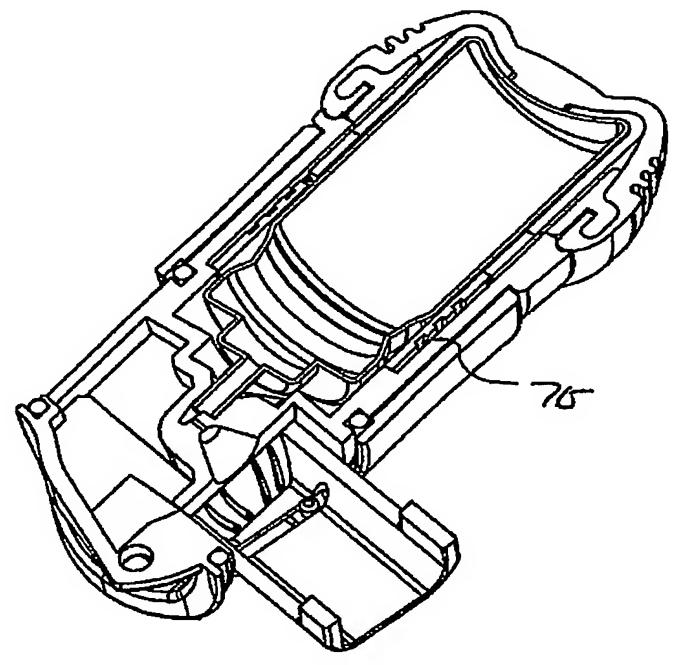
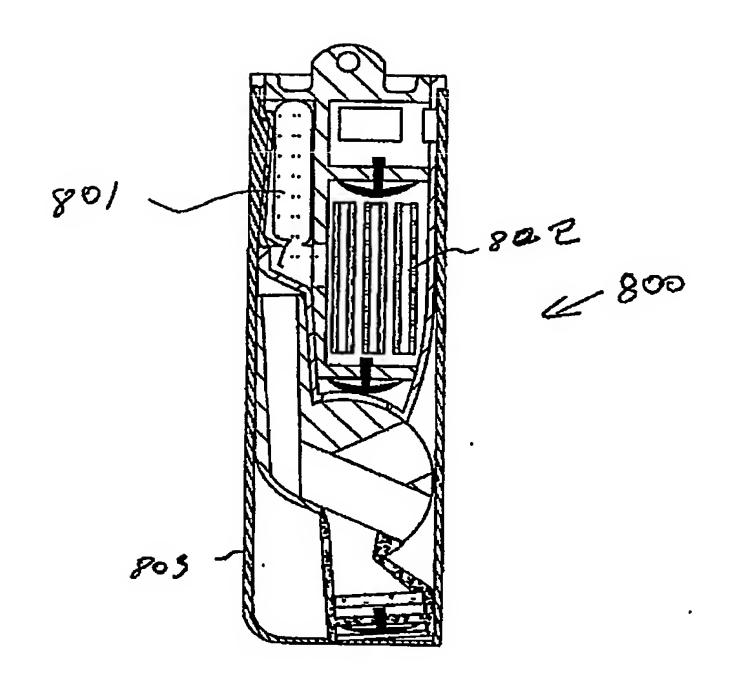
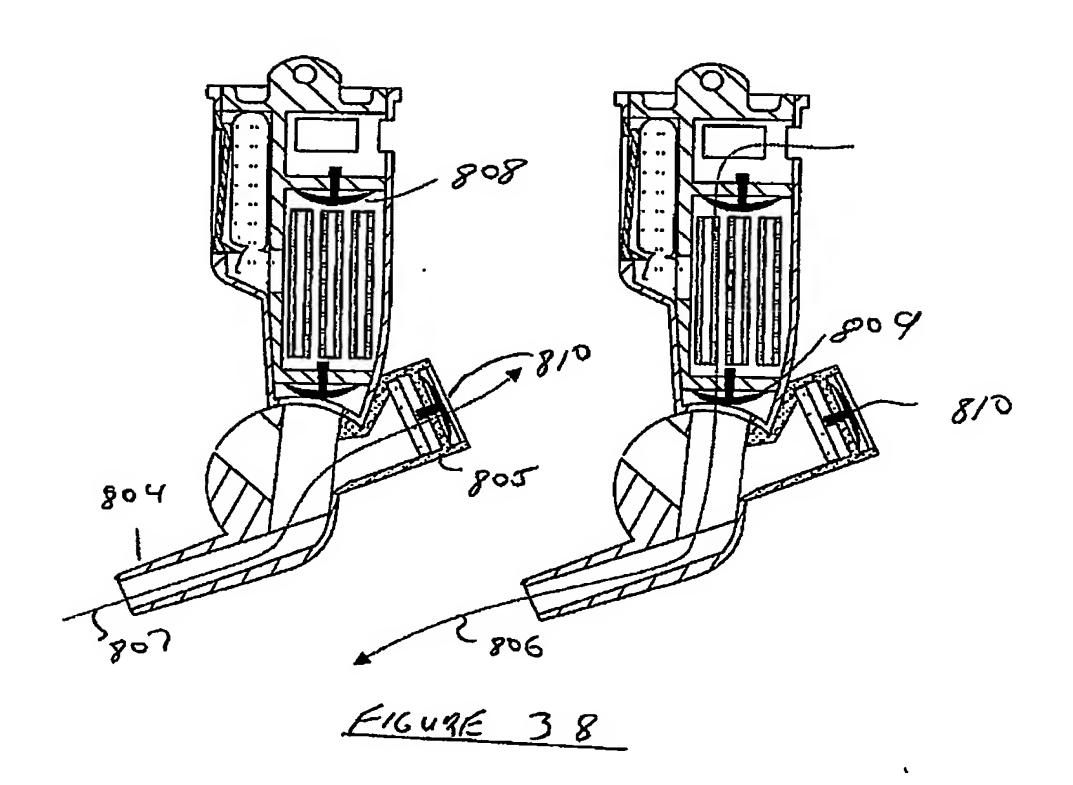


FIGURE 37





## This Page is Inserted by IFW Indexing and Scanning Operations and is not part of the Official Record

## **BEST AVAILABLE IMAGES**

Defective images within this document are accurate representations of the original documents submitted by the applicant.

Defects in the images include but are not limited to the items checked:

## IMAGES ARE BEST AVAILABLE COPY.

As rescanning these documents will not correct the image problems checked, please do not report these problems to the IFW Image Problem Mailbox.